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IN THE UNITED STATES DISTRICT COURT  
 FOR THE DISTRICT OF NEW JERSEY

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UNITED STATES OF AMERICA,  
 et al. EX REL. JESSICA PENELOW  
 and CHRISTINE BRANCACCIO,  
  
 Plaintiffs,  
  
 v.  
  
 JANSSEN PRODUCTS, LP,  
  
 Defendant.

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Case No. 12-7758 (ZNQ)(JBD)

**RELATORS' MEMORANDUM OF LAW IN OPPOSITION TO  
 DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW**

## **TABLE OF CONTENTS**

TABLE OF AUTHORITIES .....	iii
INTRODUCTION.....	1
GOVERNING LEGAL STANDARDS .....	2
ARGUMENT .....	3
I. RELATORS PROVED THEIR FCA CLAIMS .....	3
A. Relators Presented Substantial Evidence of Causation .....	4
1. Relators proved that Janssen’s false and misleading marketing was a <i>substantial factor</i> in causing false claims to be submitted to government health care programs.....	4
2. Individualized proof regarding doctors and claims is not required to establish causation .....	14
3. Relators proved that the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of Janssen’s conduct .....	17
B. Relators Presented Substantial Evidence of Materiality.....	19
1. Relators introduced overwhelming evidence that Janssen’s misconduct could have affected the Government’s payment decision .....	19
2. There was no evidence that the Government had full knowledge of the fraud and agreed to continue to pay for the drugs .....	26
3. Janssen’s other arguments are irrelevant to the FCA materiality analysis and must be rejected.....	28
C. Relators Presented Substantial Evidence of Falsity.....	29
1. Relators proved that Janssen’s false and misleading OL promotions in violation of FDA law and regulations caused the submission of claims that violated a condition of reimbursement for federal healthcare programs.....	30

2.	Relators <i>also</i> proved that certain alleged uses of Prezista and Intelence were not for “medically accepted indications” .....	35
3.	Relators proved that the alleged uses of Prezista and Intelence were not “reasonable or necessary” .....	42
4.	Relators identified hundreds of thousands of false claims ...	48
II.	RELATORS PROVED THEIR “STATE-LAW” CLAIMS.....	49
A.	Relators Proved That the OL Prezista and Intelence Prescriptions were Ineligible for Reimbursement by ADAP and Medicaid .....	50
III.	THE EVIDENCE SUPPORTS THE VERDICT AND THE NUMBER OF CLAIMS .....	56
A.	The Court Applied The Correct Measure of Damages And The Jury’s Verdict Comports With The Evidence and The Instruction .....	56
B.	Relators’ Damages Model is Supported by the Evidence .....	59
C.	The Jury’s Findings On The Number Of False Claims And The Amount Of Damages Is Supported By Substantial Evidence.....	60
D.	The Jury’s Findings On Federal Damages And The Number Of Claims Must Likewise Be Upheld .....	68
IV.	JANSSEN’S OTHER ARGUMENTS SHOULD BE REJECTED .....	70
A.	The Government Action Bar and Public Disclosure Bar Do Not Apply Here.....	70
1.	The “Government Action Bar” is inapplicable.....	71
2.	The “Public Disclosure Bar” is not applicable here .....	73
B.	There is no Constitutional Bar to Relators’ Claims .....	74
V.	CONCLUSION.....	76

## **TABLE OF AUTHORITIES**

### **CASES**

<i>AIDS Healthcare Foundation, Inc. v. Okaloosa AIDS Support and Informational Services, Inc.</i> , No. 4:23CV230-MW/MAF, 2023 WL 11926188 (N.D. Fl. Oct. 10, 2023) .....	50
<i>Ansbro v. Nat’l R. R. Passenger Corp.</i> , No. CIV. A. 90-5042, 1991 WL 258831 (E.D. Pa. Dec. 3, 1991) .....	61
<i>Arkwright Mut. Ins. Co. v. Philadelphia Elec. Co.</i> , 427 F. 2d 1273 (3d Cir. 1970) .....	9
<i>Arnold’s Office Furniture, LLC v. Borden</i> , No. 5:20-CV-05470-JMG, 2023 WL 3851978 (E.D. Pa. June 6, 2023) .....	61
<i>Avaya Inc., RP v. Telecom Labs, Inc.</i> , 838 F.3d 354 (3d Cir. 2016) .....	3
<i>Ford Motor Co. v. Summit Motor Products, Inc.</i> , 930 F.2d 277 (3d Cir. 1991) .....	61
<i>In re Actimmune Mktg. Litig.</i> , 614 F. Supp. 2d 1037 (N.D. Cal. 2009) .....	15
<i>In re Avandia Marketing, Sales Practices and Prod. Liab. Litig.</i> , 804 F.3d 633 (3d Cir. 2015) .....	16
<i>In re Avandia Marketing, Sales Practices and Products Liability Litigation</i> , No. 2007-MD-1871, 2011 WL 13576 (E.D. Pa. Jan. 4, 2011) .....	8
<i>In re Lemington Home for the Aged</i> , 777 F.3d 620 (3d Cir. 2015) .....	3
<i>In re National Prescription Opiate Litigation</i> , No. 1:17-MD-2804, 2019 WL 4043943 (N.D. Ohio Aug. 26, 2019) .....	8
<i>In re Neurontin Marketing and Sales Practices Litigation</i> , 712 F. 3d 21 (1st Cir. 2013) .....	8, 15-16

<i>In re Scrap Metal Antitrust Litig.</i> , 527 F.3d 517 (6th Cir. 2008).....	67
<i>In re Urethane Antitrust Litig.</i> , 768 F.3d 1245 (10th Cir. 2014).....	67
<i>In re Zyprexa Prods. Liab. Litig.</i> , 671 F. Supp. 2d 397 (E.D.N.Y. 2009).....	15
<i>Lightning Lube, Inc. v. Witco Corp.</i> , 4 F.3d 1153 (3d Cir. 1993).....	3
<i>Mason v. Medline Indus., Inc.</i> , 731 F. Supp. 2d 730 (N.D. Ill. 2010) .....	12
<i>Medcom Holding v. Baxter Travenol Labs., Inc.</i> , 106 F.3d 1388 (7th Cir. 1997).....	67
<i>Motter v. Everest &amp; Jennings, Inc.</i> , 883 F.2d 1223 (3d Cir.1989).....	61
<i>NAACP v. North Hudson Regional Fire &amp; Rescue</i> , 665 F.3d 464 (3d Cir. 2011).....	8
<i>New Mkt. Inv. Corp. v. Fireman’s Fund Ins. Co.</i> , 774 F. Supp. 909 (E.D. Pa. 1991) .....	61
<i>R.S.E., Inc. v. Pennsy Supply, Inc.</i> , 523 F. Supp. 954 (M.D. Pa. 1981) .....	65-66
<i>Redland Soccer Club, Inc. v. Dept. of Army</i> , 55 F.3d 827 (3d Cir. 1995).....	9
<i>Reeves v. Sanderson Plumbing Products, Inc.</i> , 530 U.S. 133 (2000) .....	2-3
<i>Reynolds v. Univ. of Pa.</i> , 747 F. Supp. 2d 522 (E.D. Pa. 2010) .....	2

<i>Riley v. St. Luke’s Episcopal Hosp.</i> , 252 F.3d 749 (5th Cir. 2001).....	75-76
<i>Russo v. Ballard Med. Prods.</i> , 550 F.3d 1004 (10th Cir. 2008).....	67
<i>Sidney Hillman Health Center of Rochester v. Abbott Laboratories</i> , 873 F. 3d 574 (7th Cir. 2017).....	18
<i>Steamfitters Loc. Union No. 420 Welfare Fund v. Philip Morris, Inc.</i> , 171 F.3d 912 (3d Cir. 1999).....	18
<i>Strom ex rel. U.S. v. Scios, Inc.</i> , 676 F. Supp. 2d 884 (N.D. Cal. 2009) .....	34
<i>Sturgeon v. Pharmerica Corp.</i> , 438 F.Supp.3d 246 (E.D. Pa. 2020) .....	72
<i>Tuf Racing Prods., Inc. v. Am. Suzuki Motor Corp.</i> , 223 F.3d 585 (7th Cir. 2000).....	68
<i>United States ex rel. Bennett v. Biotronick, Inc.</i> , 876 F.3d 1011 (9th Cir. 2017).....	72
<i>United States ex rel. Bergman v. Abbot Laboratories</i> , 995 F. Supp. 2d 357, 362 (E.D. Pa. 2014) .....	5
<i>United States ex rel. Brown v. Celgene</i> , 2:10-cv-03165 (C.D. Cal. June 12, 2014) .....	14-16
<i>United States ex rel. Buth v. Pharmerica Corp.</i> , No. 09-C-0720, 2014 WL 4355342 (E.D. Wis. 2014).....	40, 44, 49
<i>United States ex rel. Butler v. Shikara</i> , No. 20-80483-CV (S.D. Fla. Sept. 6, 2024).....	76
<i>United States ex rel. Cantekin v. Univ. of Pittsburgh</i> , 192 F.3d 402 (3d Cir. 1999).....	16

<i>United States ex rel. Chorchos for Bankruptcy Estate of Fabula v. Am. Med. Response, Inc.,</i> 865 F.3d 71 (2d Cir. 2017).....	73
<i>United States ex rel. Colquitt v. Abbott Labs,</i> No. 3:06-CV-1769-M, 2016 WL 80000 N.D. Tex. Jan. 7, 2016).....	14
<i>United States ex rel. Drakeford v. Tuomey,</i> 792 F.3d 364 (4th Cir. 2015).....	57-59
<i>United States ex rel. Druding v. Care Alternatives,</i> 952 F.3d 89 (3d Cir. 2020).....	47
<i>United States ex rel. Feldman v. City of New York,</i> 808 F. Supp. 2d 641 (S.D.N.Y. 2011).....	13
<i>United States ex rel. Franklin v. Parke-Davis, Div. of Warner- Lambert Co.,</i> 147 F. Supp. 2d 39 (D. Mass. 2001) .....	12, 16
<i>United States ex rel. Franklin v. Parke-Davis, Div. of Warner- Lambert Co.,</i> No. CIV.A. 96- 11651PBS, 2003 WL 22048255 (D. Mass. Aug. 22, 2003). 15-16	
<i>United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh, Pennsylvania,</i> 728 Fed. Appx. 101 (3d Cir. 2018) .....	32
<i>United States ex rel. Hinkle v. Caris Healthcare, L.P.,</i> No. 3:14-CV-212-TAV-HBG, 2017 WL 3670652 (E.D. Tenn. May 30, 2017) .34	
<i>United States ex rel. Kelly v. Boeing Co.,</i> 9 F.3d 743 (9th Cir. 1993).....	75
<i>United States ex rel. Kester v. Novartis Pharmaceuticals Corp.,</i> 41 F. Supp. 3d 323 (S.D.N.Y. 2014).....	39
<i>United States ex rel. Kreindler &amp; Kreindler v. United Techs. Corp.,</i> 985 F.2d 1148 (2d Cir. 1993).....	75
<i>United States ex rel. Lutz v. BlueWave Healthcare Consultants, Inc.,</i> No. 9:11-CV-1593-RMG, 2018 WL 11282049 (D.S.C. May 23, 2018) .....	58

<i>United States ex rel. Marcus v. Hess</i> , 317 U.S. 537 (1943) .....	13
<i>United States ex rel. Maur v. Hage-Korban</i> , 981 F.3d 516 (6th Cir. 2020) .....	26
<i>United States ex rel. May v. Purdue Pharma L.P.</i> , 737 F.3d 908 (4th Cir. 2013) .....	73
<i>United States ex rel. Petratos v. Genentech, Inc.</i> , 141 F. Supp. 3d 311 (D.N.J. 2015). ....	51
<i>United States ex rel. Petratos v. Genentech, Inc.</i> , 855 F.3d 481 (3d Cir. 2017) .....	6-7, 26, 46-47, 51
<i>United States ex rel. Polansky v. Pfizer, Inc.</i> , 822 F.3d 613, (2d Cir. 2016) .....	11, 53
<i>United States ex rel. Polansky v. Exec. Health Res., Inc.</i> , 599 U.S. 419, (2023) .....	75
<i>United States ex rel. Schmidt v. Zimmer, Inc.</i> , 386 F.3d 235 (3d Cir. 2004) .....	5-7, 13-14, 16-17, 39
<i>United States ex rel. Stone v. Rockwell Int’l Corp.</i> , 282 F.3d 787 (10th Cir. 2002) .....	75
<i>United States ex rel. Streck v. Takeda Pharm. Am., Inc.</i> , 2023 WL 3093476 (N.D. Ill. Apr. 26, 2023) .....	25
<i>United States ex rel. Taxpayers Against Fraud v. Gen Elec. Co.</i> , 41 F.3d 1032 (6th Cir. 1994) .....	75
<i>United States ex rel. Travis v. Gilead Scis., Inc.</i> , 596 F. Supp. 3d 522 (E.D. Pa. 2022) .....	51
<i>United States ex rel. Webb v. Miller Fam. Enter.</i> , No. 1:13-CV-00169-DBH, 2014 WL 6611012 (D. Me. July 2, 2014) .....	39

<i>United States ex. rel. S. Praver and Co. v. Fleet Bank of Maine,</i> 24 F.3d 320 (1st Cir. 1994) .....	72
<i>United States ex rel. Zafirov v. Florida Medical Associates, LLC,</i> No. 8:19-cv-1236, 2024 U.S. Dist. LEXIS 176626 (M.D. Fla. Sept. 30, 2024) ..	76
<i>United States v. AIDS Healthcare Foundation, Inc.,</i> No. 14-CV-61301-KMW, 2016 WL 11783286 (S.D. Fl. July 19, 2016) .....	50
<i>United States v. Albinson,</i> No. CIV. 09-1791 DRD, 2010 WL 3258266 (D.N.J. Aug. 16, 2010) .....	5
<i>United States v. Bornstein,</i> 423 U.S. 303 (1976) .....	13, 59
<i>United States v. Care Alternatives,</i> 81 F. 4th 361 (3d Cir. 2023).....	19, 26
<i>United States v. Greenfield v. Medco Health Solutions, Inc.,</i> 880 F. 3d 89 (3d Cir. 2018).....	7
<i>United States v. Mackby,</i> 339 F.3d 1013 (9th Cir. 2003).....	57
<i>United States v. President &amp; Fellows of Harvard Coll.,</i> 323 F. Supp. 2d 151 (D. Mass. 2004) .....	13
<i>United States v. Robinson,</i> No. CV 13-27-GFVT, 2016 WL 7030447 (E.D. Ky. July 8, 2016) .....	58
<i>United States v. Rogan,</i> 517 F.3d 449 (7th Cir. 2008).....	8, 57
<i>United States v. Shulman,</i> 624 F.2d 384 (2d Cir. 1980).....	21
<i>Universal Health Servs., Inc. v. United States ex rel. Escobar</i> 579 U.S. 176, (2016) .....	19-21, 32

<i>Vermont Agency of Nat. Res. v. United States ex rel. Stevens</i> , 529 U.S. 765, 774 (2000) .....	75
<i>Webb ex rel. United States v. Miller Fam. Enter.</i> , No. 1:13-CV-00169-DBH, 2014 WL 6611065 (D. Me. Nov. 20, 2014).....	39

## STATUTES

21 U.S.C. § 321(n) .....	31
21 U.S.C. § 352(a).....	31
21 U.S.C. §§ 331(a).....	31
21 U.S.C. §§ 331(b) .....	31
31 U.S.C. § 3729(a)(1)(A) .....	13, 39
31 U.S.C. § 3729(a)(1)(B).....	13, 39
31 U.S.C. § 3730(e)(4) .....	26
31 U.S.C. § 3730(e)(4)(A) .....	73-74
31 U.S.C. §3730(b) .....	27
31 U.S.C.A. § 3729(b)(2)(A)(ii) .....	39
42 U.S.C. § 256b .....	54
42 U.S.C. § 1396r-8(k)(2) .....	54
42 U.S.C. §§ 1395w-102(e)(1).....	36
42 USC §§ 1395w-102(e)(3) .....	42
42 U.S.C. §§ 1395w-102(e)(3)(A) .....	36
42 USC §§ 1395y(a)(1)(A) .....	42
42 USC §§ 1396w-102(e) .....	35

42 USC §§ 1396r-8(k)(6) .....	35
-------------------------------	----

## RULES

2 C.F.R. § 200.403(a) .....	54
45 C.F.R. § 75.403(a) .....	54
42 C.F.R. 50.504 .....	54

## OTHER AUTHORITIES

Manual ch. 6 § 10.6 .....	37
<i>Prosser and Keeton on Torts</i> § 44, at 303–04 (5th ed. 1984) .....	17
Restatement (Second) of Torts § 443 (1965) .....	17
Ryan White HIV/AIDS Program, AIDS Drug Assistance Program (ADAP) Manual .....	54
United States Dept. of Justice, Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013) .....	2
United States Dept. of Justice, Shire Pharmaceuticals LLC to Pay \$56.5 Million to Resolve False Claims Act Allegations Relating to Drug Marketing and Promotion Practices (Sept. 24, 2014) .....	2

Relators Jessica Penelow and Christine Brancaccio hereby oppose Defendant Janssen Products, LP's Motion for Judgment as a Matter of Law, filed on August 12, 2024. Dkt. 473. For the reasons stated below, Janssen's Motion should be denied in its entirety.

### **INTRODUCTION**

Through its Motion, Janssen seeks the extraordinary relief of overturning the jury verdict entered in this case on June 13, 2024. *See* Dkt. 435. The eight-member jury unanimously found that Relators have proven by a preponderance of the evidence that Janssen violated the federal and states' False Claims Acts ("FCA") by unlawfully promoting its HIV drugs Prezista and Intelence during the relevant period of June 2006 through 2014 (the "Relevant Period"). The jury further determined the amounts of damages that the federal and state governments sustained as a result of Janssen's conduct, as well as the number of false claims that Janssen caused to be submitted to the government for reimbursement. *Id.* The jury reached its verdict after more than a five-week trial spanning from May 6 to June 13, 2024, during which Relators' counsel presented a mountain of evidence through twelve fact witnesses (all of whom had been employed by Janssen), five experts, and hundreds of Janssen's own documents. The jury deliberated for over two full days, and it made multiple requests for witness testimony and other information from the Court before delivering its verdict.

Despite the voluminous substantive evidence presented by Relators establishing each element of their claims, Janssen now argues to the Court that there is “no evidence” to support Relators’ claims. Def. Br. at 1–2.<sup>1</sup> Janssen also rehashes many of the same legal arguments that this Court has previously rejected, and/or that are contrary to law. Based on the trial record, governing legal standards, and applicable law, Janssen’s Motion should be denied in its entirety.<sup>2</sup>

### **GOVERNING LEGAL STANDARDS**

A Rule 50(b) motion requires the court to “review all the evidence in the record.” *Reynolds v. Univ. of Pa.*, 747 F. Supp. 2d 522, 534 (E.D. Pa. 2010) (citing *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150 (2000)). Judgment

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<sup>1</sup> “Def. Br” refers to Janssen’s accompanying Memorandum of Law, at Dkt 473-1.

<sup>2</sup> Relators’ theory of liability is not novel in that there have been numerous settlements of FCA cases over the years involving OL promotion of drugs within the same disease state for which the drug was FDA-approved. *See, e.g.*, United States Dept. of Justice, Shire Pharmaceuticals LLC to Pay \$56.5 Million to Resolve False Claims Act Allegations Relating to Drug Marketing and Promotion Practices (Sept. 24, 2014), <https://www.justice.gov/opa/pr/shire-pharmaceuticals-llc-pay-565-million-resolve-false-claims-act-allegations-relating-drug> (settling allegations of false promotion three ADHD-treatment drugs for patients with ADHD by overstating efficacy and minimizing “abuseability”); *see also* United States Dept. of Justice, Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013), <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations#:~:text=As%20part%20of%20today's%20resolution,off%2Dlabel%20marketing%20of%20Natrecor> (settling allegations with Scios, a J&J subsidiary, for illegal promotion of a heart failure drug to patients with a less severe form of heart failure than the drug was approved for).

as a matter of law “should be granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability.” *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993) (citation omitted). The motion must be denied if the record contains “that minimum quantity of evidence from which a jury might reasonably afford relief.” *In re Lemington Home for the Aged*, 777 F.3d 620, 626 (3d Cir. 2015) (citation omitted).

Overturning a jury’s verdict through a Rule 50(b) motion is extraordinary relief that should be granted “sparingly.” *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 373 (3d Cir. 2016). “Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.” *Id.* (quoting *Reeves*, 530 U.S. at 150–51). Thus, “although the court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury is not required to believe.” *Id.*

## **ARGUMENT**

### **I. RELATORS PROVED THEIR FCA CLAIMS**

Janssen argues that “the evidence fails to support the portion of the jury’s verdict in favor of Relators” as to causation, materiality, and falsity. Def. Br. at 7–

8.<sup>3</sup> Because the record contained sufficient evidence to support the jury’s findings as to all of these elements, Janssen’s Rule 50(b) challenges fail.

**A. Relators Presented Substantial Evidence of Causation**

The Court correctly instructed the jury that Janssen could be found to have caused the submission of a claim to the government payors if “(1) the conduct was a *substantial factor* in inducing providers to submit claims for reimbursement, and (2) the submission of claims for reimbursement was *reasonably foreseeable or anticipated as a natural consequence* of Janssen’s conduct.” See Dkt. 424-11 at 35 (Instruction No. 19.2, “Causation”) (emphasis added). Relying upon the wrong legal standard, Janssen now argues that Relators failed to prove that Janssen was the “but for” or proximate cause of the submission of false claims to Medicare. Def. Br. at 8. Because the record was more than sufficient for the jury to find that Janssen caused the submission of false claims under the Third Circuit’s “substantial factor” test, Janssen’s challenge fails.

**1. Relators proved that Janssen’s false and misleading marketing was a *substantial factor* in causing false claims to be submitted to government health care programs.**

Janssen argues that Relators failed to produce substantial evidence that Janssen’s conduct was the “but-for cause” of the submission of any false claim for reimbursement. Def. Br. at 8. Janssen’s “but-for” argument is both incorrect and

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<sup>3</sup> “Def. Br” refers to Janssen’s accompanying Memorandum of Law, at Dkt 473-1.

irrelevant. As this Court recognized in denying Janssen’s motion for summary judgment, causation is satisfied under the FCA if the defendant’s conduct was a “substantial factor” in producing the false claims and it was “foreseeable” that false claims would result from such conduct. *See* Dkt. 291 at 19–21; *see also United States ex rel. Schmidt v. Zimmer*, 386 F.3d 235, 244 (3d Cir. 2004) (employing the “substantial factor/foreseeability” test for FCA causation in marketing context); *see also United States v. Albinson*, No. CIV. 09-1791 DRD, 2010 WL 3258266 at \*11–12 (D.N.J. Aug. 16, 2010) (same).<sup>4</sup>

Nonetheless, Janssen attempts to supplant the Third Circuit’s “substantial factor” test for causation in FCA cases with a “but-for” cause standard that contradicts the Court’s Instruction No. 19.2 (“Causation”) to the jury—an instruction that Janssen does not even challenge in any of its post-trial briefing. Def. Br. at 8. Initially, Janssen acknowledges that the proper causation standard in an FCA case is whether “Janssen’s alleged conduct was a ‘substantial factor’ in causing the submission of false claims to Medicare.” Def. Br. at 8. (citing *United States ex. Rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244-45 (3d Cir. 2004)). In the next sentence, however, Janssen contends that Relators “thus” had the burden of proving that (1)

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<sup>4</sup> *See United States ex rel. Bergman v. Abbot Laboratories*, 995 F. Supp. 2d 357, 362, 368 (E.D. Pa. 2014) (“The Third Circuit has held that in order to properly allege causation, the illegal marketing scheme must be a ‘substantial factor’ in influencing third parties, such as physicians, to file false claims.”).

Janssen was the “*but-for*” cause of the submission of false claims and (2) the “proximate cause” of the submission of those claims. *Id.* (emphasis added). Janssen supports both contentions with a bare citation to one page of the Third Circuit’s decision in *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 491 (3d Cir. 2017). *Id.* But the *Petratos* court did not replace the “substantial factor” test the Third Circuit held applicable to the FCA in *Schmidt* with the “but-for” test, as Janssen casually implies.

Instead, Janssen’s brief borrows the relator’s rejected and erroneous argument in *Petratos* and attempts to make it the Third Circuit’s test for causation. In *Petratos*, the relator argued that he could establish the *materiality* element by proving that “the alleged fraud was the ‘but for’ cause of the submitted claim.” 855 F.3d at 491. The court observed that the relator “conflates materiality with causation, a separate element of a False Claims Act cause of action.” *Id.* It further pointed out that *the relator’s theory* was illogical because “but-for” causation could not alone suffice even for the causation element—which requires a showing of *proximate cause* (foreseeability) as well. *Id.* The *Petratos* court did *not* hold that the relator’s “but for” causation theory is the proper standard for causation in FCA cases in rejecting the relator’s errant theory as to materiality. The Third Circuit’s “substantial factor”

test adopted in *Schmidt* applies—not “but for” causation.<sup>5</sup>

Under the correct test, and as the Court instructed the jury, Relators proof was far more than sufficient to establish that Janssen’s illegal OL marketing was a “substantial factor” in “in inducing providers to submit claims for reimbursement.” See Final Jury Instructions, Instruction No. 19.2. Relators produced voluminous evidence that Janssen’s false and misleading marketing induced physicians to submit claims for reimbursement to government payors, and that those claims were not only foreseeable and anticipated but were Janssen’s intended result. For instance, Relators presented evidence to the jury showing that, *inter alia*: (1) Janssen engaged in a top-down, nationwide off-label (“OL”) marketing scheme for Prezista and Intelence over a period of almost nine years; (2) the very purpose of Janssen’s systematic OL scheme was to cause doctors to increase their prescriptions of Prezista and Intelence, as Janssen’s own documents and trial witnesses demonstrated; (3) Janssen’s sales representatives and managers observed an increase in doctors’ prescriptions after they delivered the OL messages to them; (4) marketing reports by PILM, a third-party marketing research firm retained by Janssen, state that Janssen’s sales force had the highest effectiveness of any sales force in causing “lift” or an increase in prescriptions through their promotion; (5) Relators’ pharmaceutical marketing

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<sup>5</sup> See also *United States v. Greenfield v. Medco Health Solutions, Inc.*, 880 F. 3d 89, 96 (3d Cir. 2018) (decided after *Petratos* and rejecting “but for” test with respect to the AKS under the FCA).

expert, George Sillup, opined that Janssen’s specific OL marketing messages caused doctors to prescribe Prezista and Intelence OL; (6) Relators’ data expert, Ian Dew, identified hundreds of thousands of “prescription drug event” (“PDE”) data demonstrating claims for the OL prescriptions of Prezista and Intelence from influenced physicians submitted to CMS for reimbursement; (7) Relators’ causation and damages expert Israel Shaked performed statistical analyses which identified the thousands of doctors who were subjected to Janssen’s marketing, and demonstrated that those “influenced” doctors prescribed the drugs OL at much higher rates than doctors who were not contacted by Janssen;<sup>6</sup> and (8) Shaked’s calculations showed that thousands of OL prescriptions were written by “influenced” doctors and then

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<sup>6</sup> *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (holding, in FCA case, that the defendant’s “argument that the district judge had to address each of the 1,812 claim forms is a formula for paralysis” and that “[s]tatistical analysis should suffice”) (emphasis added); *In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 21, 42 (1st Cir. 2013) (“[C]ourts have long permitted parties to use statistical data to establish causal relationships.”) (collecting cases) (affirming jury’s finding of causation between OL marketing and prescriptions based on expert’s statistical analyses); *In re National Prescription Opiate Litigation*, No. 1:17-MD-2804, 2019 WL 4043943 at \*5–6 (N.D. Ohio Aug. 26, 2019) (holding experts can rely on statistical correlations to infer causation); *Celgene*, 226 F. Supp. 3d at 1039–40 (holding a jury could find causation between OL marketing and prescriptions based, in part, on statistical analysis of plaintiff’s expert); *NAACP v. North Hudson Regional Fire & Rescue*, 665 F.3d 464, 477 (3d Cir. 2011) (“Statistical disparities alone can raise an inference of causation.”); *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, No. 2007-MD-1871, 2011 WL 13576 at \*4 (E.D. Pa. Jan. 4, 2011) (finding “the experts have sufficient statistically significant data to support their causal inferences”).

submitted to the government for reimbursement.<sup>7</sup> The Court discussed some of this evidence when denying Janssen’s motion for summary judgment. Dkt 291 at 20–21. Causation is a quintessential fact issue for the jury to decide,<sup>8</sup> and based on Relators’ evidence presented at trial, the jury was entitled to find that Janssen’s conduct was a “substantial factor in inducing prescribers to submit claims for reimbursement.”

Nonetheless, after applying the wrong causation standard, Janssen ignores the Court’s instruction to the jury regarding whether its conduct was a “*substantial factor*” in inducing *providers* to submit claims for reimbursement, *see* Dkt. 414-11 at 35 (Instruction No. 19.2, “Causation”), and argues that Relators failed to produce substantial evidence that Janssen was the “*but-for cause*” of the submission of a false claim “*by a Part D plan sponsor to CMS.*” Def. Br. at 8 (emphasis added). Janssen contends that “Relators needed to prove not merely that Janssen persuaded doctors to prescribe off-label, but that Janssen engaged in conduct that somehow subverted Part D plan sponsors’ processes for identifying and weeding out prescriptions that

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<sup>7</sup> For point (1), *see* the trial testimony of Penelow, Brancaccio, Wilhelm, Strand, Graham, Grooms, and Holshoe. For the remaining points, *see* RX178 at 2; 5/15/2024 Trial Tr. at 1708:8–1709:13; 1726:20–1727:6; 5/22/2024 Trial Tr. at 3255:15–3256:23; 5/23/2024 Tr. at 3508:4–16; 5/30/2024 Tr. at 4726:11–4727:23; 5/9/2024 Trial Tr. at 748:25–749:13; 5/22/2024 Tr. at 3046:24–3047:9; 6/3/2024 Tr. at 5410:6–11, 5443:11–5444:6, 5447:2–6, 5448:10–5449:18, 5476:7–5477:9, 5480:25–5485:23.

<sup>8</sup> *See Redland Soccer Club, Inc. v. Dept. of Army*, 55 F.3d 827, 851 (3d Cir. 1995) (“Causation in fact is normally a question for the jury[.]”); *see also Arkwright Mut. Ins. Co. v. Philadelphia Elec. Co.*, 427 F. 2d 1273, 1275 (3d Cir. 1970) (same).

are not eligible for reimbursement under Medicare.” *Id.* at 9.

Janssen’s manufactured requirement of proof, under the wrong standard of causation, is not at all what Relators “needed to prove” under the Court’s instruction for causation. Whether Janssen’s conduct was a “substantial factor” in inducing doctors to submit claims for reimbursement has nothing to do with whether Janssen was the “but-for” cause of downstream, intermediary Part D plan sponsors submitting claims to CMS. Janssen cites no authority for its fictitious requirement that Relators must prove how Janssen’s fraudulent marketing impacted Part D sponsors’ “processes.” That is because there is none.

Janssen next relies upon an amicus brief filed by the United States in the Ninth Circuit to assert that Relators “must” show that Janssen made false statements “material to reimbursability.” Def. Br. at 10. This too is incorrect. While the amicus brief states that a drug company *may* be liable under the FCA where it makes false or misleading statements material to reimbursability, the United States was not asserting that this conduct is the *exclusive* basis of FCA liability; it was simply providing one example of how a company may violate the Act based on the facts in that case. *See* Def. Br., Ex. 1 at 11–12.<sup>9</sup>

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<sup>9</sup> The United States’ amicus brief is favorable to Relators’ position here. The United States, under the “*substantial factor*” test, describes how a drug company’s marketing to doctors may cause the submission of false claims to the government and says nothing about a requirement of proof relating to Part D plan sponsors. *See* Def. Br. Ex. 1, at 12–13 (“The proximate connection between the drug company’s

In the absence of any direct legal authority relating to intermediary plan sponsors, Janssen attempts to reason by analogy by citing to *United States ex rel. Polansky v. Pfizer*, 822 F.3d 613 (2d Cir. 2016), which does not stand for any of the propositions Janssen argues. In *Polansky*, the Second Circuit affirmed the district court's dismissal of the relator's complaint for failing to identify a false claim because the relator alleged that the OL promotion contradicted non-mandatory *guidelines*, rather than the drug's label. *Id.* at 616–20. The alleged OL promotion *was not OL at all*. Notably, the court did not address causation standards, Part D sponsors, or false and misleading OL marketing that contradicted the drug's label or minimized its side effects.

Relators here proved that Janssen's fraudulent promotion of Prezista and Intelence induced physicians to prescribe the drugs in violation of FDA law, for uses that were not proven safe and effective, were not medically accepted or medically necessary, and were potentially dangerous. Regardless of how the relator in *Polansky* might have proven his case, in this case ***there was a trial***, and the evidence supported the jury's findings that Janssen induced providers to submit false claims for reimbursement.

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actions and the submission of the false claim is clear where the drug company's false or misleading marketing activities or kickbacks are *designed to induce the provider to prescribe or administer the drug and submit false claims to pay for it.*") (emphasis added).

Caselaw is clear that proof of a fraudulent OL marketing scheme *directed at doctors* will establish causation despite several links and intermediary players involved further down the claim submission chain and the fact that doctors or pharmacies (or Part D sponsors) are alleged to have exercised their own judgment or discretion. The court in *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 52–53 (D. Mass. 2001) (“*Franklin I*”) addressed this precise point:

The gravamen of Relator’s claim is that Parke–Davis engaged in an unlawful course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the government under Medicaid. . . . Defendant argues that Relator has not stated a claim because he has not accounted for the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions. In other words, Defendant argues that—as a matter of law—Relator’s allegations cannot establish the causation requirement of the FCA because the actions of these professionals were an intervening force that breaks the chain of legal causation. Under black letter law, however, such an intervening force only breaks the causal connection when it is unforeseeable. . . . [W]hen all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.

*Id.* (internal citations omitted).<sup>10</sup> Here, there is *overwhelming proof* that Janssen’s marketing changed physicians’ prescribing behavior and led to increased OL

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<sup>10</sup> See also *Mason v. Medline Indus., Inc.*, 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010) (“The wealth of case law supports the proposition that the FCA reaches

prescriptions of Prezista and Intelence submitted to government payors for reimbursement, including evidence drawn from extensive expert analyses that Janssen itself paid for in real time.<sup>11</sup>

Janssen's argument is also contrary to the statutory language of the FCA itself. Under the law, a defendant can be liable under the FCA for "causing" the presentment of false claims. 31 U.S.C. § 3729(a)(1)(A), (B). Such liability attaches here where Janssen engaged in an OL scheme that was a substantial factor in causing others, including Part D sponsors, to present false claims to the government.<sup>12</sup> As the Third Circuit has held, "the crucial issue was whether the defendants knowingly

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claims that are rendered false by one party but submitted to the government by another") (collecting cases).

<sup>11</sup> See Dkt. 75 at 6–8 (SOI) ("Fraud directed at physicians may therefore establish FCA liability if government reimbursement was a reasonably foreseeable result").

<sup>12</sup> See, e.g., *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544–545 (1943) (The provisions of the FCA, including its prohibition on *causing* the presentment of false claims, "indicate a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government"); *United States v. Bornstein*, 423 U.S. 303, 309 (1976) ("It is settled that the [FCA] . . . gives the United States a cause of action against a subcontractor who causes a prime contractor to submit false claims to the Government"); *Schmidt*, 386 F.3d at 244–245 (holding a defendant is liable for a marketing scheme that it knew would result in others submitting false claims); *United States ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 650 (S.D.N.Y. 2011) (It "is well-established that the FCA reaches claims that are rendered false by one party, but submitted to the government by another."); *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 187 (D. Mass. 2004) (holding "a defendant may be liable if it operates under a policy that causes others to present false claims to the government").

assisted in the presentation of false claims,” and therefore “the knowledge and conduct of the defendant were what mattered and the outcome did not turn on whether the actual presenters were ‘duped’ or participated in the fraudulent scheme.” *Schmidt*, 386 F.3d at 244. Relators presented evidence at trial from which the jury was entitled to conclude that Janssen’s illegal conduct caused false claims to be submitted to the government, whether by a doctor, a pharmacy, or a Part D sponsor, and regardless of the knowledge of any of those downstream parties. Under controlling Third Circuit law, no further proof regarding Janssen’s influence over Part D sponsors is required.

**2. Individualized proof regarding doctors and claims is not required to establish causation.**

Janssen next argues that Relators failed to present individualized proof at the doctor-by-doctor or claim-by-claim level that Janssen’s unlawful marketing of Prezista and Intelence caused any one doctor to prescribe those drugs, as opposed to some other cause. Def. Br. at 12–15. Janssen ignores the relevant FCA authority and the entirety of the trial record.

First, evidence of direct causation at a physician-by-physician or claim-by-claim level is not required to prove causation in an FCA case.<sup>13</sup> This Court

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<sup>13</sup> See, e.g., *United States ex rel. Colquitt v. Abbott Labs.*, No. 3:06-CV-1769-M, 2016 WL 80000, at \*7 (N.D. Tex. Jan. 7, 2016) (denying summary judgment on causation without requiring evidence that any provider ever relied on information provided by defendants); *Celgene*, 226 F. Supp. 3d at 1040–1041; *United States ex*

previously rejected this exact argument. *See* Dkt. 291 at 19. Janssen’s citations to inapposite cases addressing the need for individualized proof in the class action context do not help its cause.<sup>14</sup>

Second, doctors’ alleged independent decision-making does not break the causal chain. Relators presented a mountain of evidence that Janssen engaged in a nationwide OL marketing scheme that was designed to influence doctors’ prescribing behavior. Relators proved that marketing influences doctors generally and that Janssen’s false and misleading marketing specifically influenced doctors. *See, e.g.*, 5//22/24 Tr. 3098:21–2099:5 (Sillup). They further proved that doctors *specifically influenced* by Janssen’s hundreds of thousands of marketing contacts prescribed Prezista and Intelence OL at double the rate of non-influenced doctors.<sup>15</sup>

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*rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, No. CIV.A. 96-11651PBS, 2003 WL 22048255, at \*5 (D. Mass. Aug. 22, 2003) (“*Franklin II*”); United States’ Statement of Interest, *United States ex rel. Brown v. Celgene*, 2:10-cv-03165, Dkt. 129 at 13 (C.D. Cal. June 12, 2014), United States’ Statement of Interest, *Celgene*, 2:10-cv-03165, Dkt. 328 at 13–14 (C.D. Cal. Aug. 29, 2016) (“Indeed, because off label marketing schemes are often large-scale endeavors targeting thousands of doctors (who rarely will admit that their medical decisions were influenced by a marketing campaign), requiring direct, individualized proof would . . . embolden drug companies to engage in large scale fraud.”).

<sup>14</sup> *See* Def. Br. at 13,14 n.4 (citing *In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397 (E.D.N.Y. 2009)) (discussing, in the structural class action context, the Individual Proof Rule that says issues of reliance, loss causation, and injury must be proven for each victim); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037 (N.D. Cal. 2009) (consumer class action alleging RICO violations).

<sup>15</sup> Janssen feebly attempts to distinguish *Neurontin*. Def. Br. at 14 n.4; 712 F.3d at 41–45 (permitting plaintiff “to use statistical data to establish [a] causal relationship”

*See, e.g.*, 6/3/24 Tr. 5456:18–5458:19 (Shaked). In an attempt to rebut this evidence, Janssen presented testimony of a few doctors who claimed they did not believe their prescribing decisions were influenced by Janssen’s OL marketing. The jury was entitled to weigh this evidence as it saw fit. *See Celgene*, 226 F. Supp. 3d at 1037, 1040 (C.D. Cal. 2016) (holding “a reasonable jury could choose to reject the physicians’ testimony that Celgene’s marketing efforts did not influence their prescribing decisions,” in light of evidence of Celgene’s systematic OL scheme).<sup>16</sup>

When all factual inferences are drawn in Relators’ favor, it is both natural and foreseeable that Janssen obtained its desired result: doctors prescribed more Prezista and Intelence OL. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 416 (3d Cir. 1999) (applying “basic principle[s] of tort law” to the FCA); *see also Schmidt*, 386 F.3d at 244–246 (holding “the intervention of a force which is a

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between fraudulent marketing and OL prescriptions). Like *Neurontin*, Shaked’s statistical analyses demonstrate the obvious: Janssen’s contacts with doctors caused OL prescriptions. Relators’ expert witness, George Sillup, and Janssen’s own documents revealed the same, in addition to other trial witnesses.

<sup>16</sup> *See also Franklin I*, 147 F. Supp. 2d at 52–53 (rejecting defendant’s argument that “the actions of the[] [physicians] were an intervening force that br[oke] the chain of legal causation”); *Franklin II*, 2003 WL 22048255 at \*4–5; *In re Avandia Marketing, Sales Practices and Prod. Liab. Litig.*, 804 F.3d 633, 645 (3d Cir. 2015) (RICO); *In re Neurontin*, 712 F.3d at 45 (RICO) (“Once a plaintiff presents evidence” that his injury is the type “that would be the expected consequence of the defendant’s wrongful conduct,” the burden shifts to the defendant to rebut this causal inference.”); Def. Br., Ex. 1, at 15 (stating “it is axiomatic” that “the exercise of judgment by the decision maker does not prevent the earlier agent’s action . . . from being the proximate cause of the harm.”).

normal consequence of a situation created by the [defendant's] conduct is not a superseding cause of harm"); *see also* D. Dobbs, et al., *Prosser and Keeton on Torts* § 44, at 303–04 (5th ed. 1984) ("The courts are quite generally agreed that [foreseeable intervening forces] will not supersede the defendant's responsibility."); *see also* Restatement (Second) of Torts § 443 (1965) ("The intervention of a force which is a normal consequence of a situation created by the actor's . . . conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about.").<sup>17</sup>

**3. Relators proved that the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of Janssen's conduct.**

Finally, Janssen argues that Relators "did not establish proximate cause." Def. Br. at 8, 15–17. This argument is meritless. Proximate cause is embodied within the foreseeability prong of the substantial factor test, which Relators have clearly satisfied here. *See Schmidt*, 386 F.3d at 244 (referencing causation principles from negligence law to arrive at substantial factor/foreseeability test). The evidence was more than sufficient for the jury to determine that the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence

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<sup>17</sup> Similarly, the Part D Sponsors' supposed independent judgment for "weeding out prescriptions" does not defeat causation. Relators provided evidence that the reimbursement of prescriptions was the intended and normal consequence of Janssen's OL marketing scheme. The jurors were entitled to weigh the evidence and find causation.

of Janssen's conduct. In fact, the evidence established that increased prescriptions of Prezista and Intelence was the very goal of Janssen's unlawful promotion. *See Hess*, 317 U.S. 537, 543–44 (“The initial fraudulent action and every step thereafter taken, pressed ever to the ultimate goal—payment of government money to persons who had caused it to be defrauded.”).

There was nothing “indirect,” “remote,” or “contingent” about Janssen's unlawful marketing causing doctors to prescribe Prezista for patients with lipid issues, Intelence once-daily, or Prezista and Intelence in treatment-naïve patients. Def. Br. at 15, 17.<sup>18</sup> At trial, Relators provided more than sufficient evidence for the jury to conclude that Janssen's nationwide nine-year OL marketing scheme was a substantial factor in causing physicians to prescribe Prezista and Intelence, and that it was reasonably foreseeable that Janssen's conduct would result in the submission of false claims to the government for reimbursement. Under established legal precedent, such proof establishes FCA causation.

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<sup>18</sup> Janssen relies on two irrelevant cases, and neither bear on whether Relators here satisfied the substantial factor/foreseeability test here. Def. Br. at 15–17; *see Sidney Hillman Health Center of Rochester v. Abbott Laboratories*, 873 F. 3d 574 (7th Cir. 2017) (affirming dismissal of a RICO claim at the pleading stage because, among other reasons, plaintiffs lacked relevant data to establish causation); *Steamfitters Loc. Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912 (3d Cir. 1999) (discussing antitrust law in the class action context).

**B. Relators Presented Substantial Evidence Of Materiality**

The Court instructed the jury that Relators were required to prove that “Janssen’s alleged off-label marketing violations were material to the Government’s payment decision,” which means that the unlawful promotion “had a natural tendency to influence, or was capable of influencing, the payment or receipt of money or property.” *See* Dkt. 424-11 at 37 (Instruction No. 19.4, “Materiality”). Janssen argues that the jury’s verdict should be overturned because Relators failed to prove materiality. Def. Br. at 17. Because the record was more than sufficient for the jury to find that Janssen’s unlawful promotion was capable of influencing the government payors’ payment decision, Janssen’s challenge fails.

**1. Relators introduced overwhelming evidence that Janssen’s misconduct could have affected the Government’s payment decision.**

Janssen starts its challenge on materiality by cherry-picking the evidence. Def. Br. at 17–20. Once again, Janssen inverts the standard for a Rule 50(b) motion and ignores the bulk of evidence in the record. The correct standard is whether there was sufficient evidence, considered in the light most favorable to *Relators*, from which the jury could find materiality. Relators far exceeded this standard at trial.

Determining materiality is “a ‘holistic,’ totality-of-the-circumstances inquiry.” *United States v. Care Alternatives*, 81 F. 4th 361, 366–67 (3d Cir. 2023) (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176,

181–182 (2016)). Courts consider factors like “whether the government has expressly designated the legal requirement at issue as a ‘condition of payment;’” “whether the alleged violation is ‘minor or insubstantial’ or instead goes to the ‘essence of the bargain’” and “whether the government made continued payments, or does so in the ‘mine run of cases,’ despite ‘actual knowledge’ of the violation.” *Id.* (citing *Escobar*, 579 U.S. at 193 n.5, 194–95).

First, Relators introduced two separate Corporate Integrity Agreements and a Settlement Agreement between Janssen and the government, *during the Relevant Period*, entered into as a result of Janssen’s alleged unlawful OL promotion of other drugs in violation of FDA laws and the FCA. RX423 (2010 CIA); RX361 (2013 CIA); RX1624 (2013 Settlement Agreement). This evidence demonstrated that Janssen was accused of promoting those drugs with false and misleading statements about their efficacy, for uses that were not approved by the FDA, and for indications that were not medically accepted in some cases or covered by Medicare, Medicaid and other federal healthcare programs. *See, e.g.*, RX1624 at 3–4. This evidence shows that, as a result of Janssen’s alleged misconduct in connection with its unlawful promotion of other drugs, it was required by the government payors to return the monies those programs paid out. *See id.*; *see also* 5/28/24 Tr. 3821:08–25 (discussing RX1624 and stating reimbursement of government payors for unlawful promotion of drugs in violation of federal law is “*the number one condition*” in

resolving that violation) (Evans). This evidence further established that compliance with FDA laws prohibiting illegal promotion by a manufacturer of unapproved or unsafe uses of its drugs is not “minor or insubstantial” but goes to the “very essence of the bargain” between the government and manufacturers. *See Escobar*, 579 U.S. at 193 n.5, 194–95.

The admissions from Janssen’s own witnesses—including its president Glen Mattes and national sales director Michael Iacobellis—were equally damning and demonstrate defendant’s knowledge that the violative conduct proven here was material to the government.<sup>19</sup> Mattes admitted that the government takes OL marketing by a pharmaceutical company “very seriously.” 5/22/24 Tr. 2923:01–09. Mattes further admitted that “ultimately, *if the government discovered that there was off-label marketing that’s taking place by a pharmaceutical company and Medicare or Medicaid has reimbursed for those drugs*,” the government “*will demand that money back*” from the manufacturer to resolve the violations. *Id.* at 10–16 (emphasis added); *see also Id.* at 2930:08–12 (“Q. The point being, sir, if there are products that are being sold for reimbursement by Medicare and Medicaid and it turns out

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<sup>19</sup> *See United States v. Shulman*, 624 F.2d 384, 392 n.17 (2d Cir. 1980) (approving district court’s instruction that “[a]dmissions or statements by a defendant are among the most effectual proofs in law. They constitute the strongest sort of evidence against the party making the admissions or statements of the facts[.]”).

that those were *sold in violation of the law, the Government is going to come back and get its money. A. Yes.*”) (discussing RX275 at 7) (emphasis added).

Iacobellis admitted that OL marketing for “a different use case,” “a different dosage,” or to “a different patient population [than] it was intended for” was “[a]bsolutely” “*not legal.*” 5/14/24 Tr. 1369:25–1370:21 (emphasis added); RX360 at 59. He further admitted that state and federal law prohibit the submission of false claims to government payors and that Janssen taught its employees that the federal government takes such matters seriously. 5/14/24 Tr. 1380:15–19, 1386:17-20 (“It’s very serious and very important, yes.”).

Numerous and detailed exhibits from Janssen’s own compliance department further proved that Janssen’s unlawful promotion of Prezista and Intelence to doctors was material to government payors’ payment decisions and that Janssen *knew it*. A sample of those exhibits includes:

- Janssen acknowledged that the healthcare industry is “unique” because it impacts the “health and safety of patients” and the government, including Medicare and Medicaid, reimburses a large percentage of all prescription products. RX275 at 7 (“The pharmaceutical industry is heavily regulated. [T]he government reimburses approx. 60% or more of all pharmaceutical products through gov funded programs such as medicare and medicaid. . . . The government is our biggest customer.”).
- Janssen admitted that the government “*does not want to cover the cost of Rx products* when they violate the following: . . . False Claims Act . . . *Sell off-label . . . Misrepresent product*” *Id.* (emphasis added).
- Janssen admitted that a manufacturer “may be implicated by the government if it *purposely provides information* to a [health care

provider] that *causes the HCP to submit false or fraudulent claims*” for the company’s products. RX360 at 12 (emphasis added). Its documents detailed numerous enforcement actions under the False Claims Act against other manufacturers for engaging in off-label promotion in violation of FDA regulations. *Id.* at 21 (Serono enforcement action), 22 (Neurontin enforcement action).

- Janssen knew that False Claims Act laws applied to manufacturers that caused false claims for payments to be submitted to government programs. *Id.* at 67.
- Janssen admitted that CMS considers “the illegal promotion of off-label drug usage through marketing, financial incentives, or other promotion campaigns” to be a “*high risk area for manufacturers in the Part D program.*” DX2069 at 17 (“Guidance Document on Medicare Part D Contracting, Sales, and Marketing”) (emphasis added). It acknowledged that Chapter 9 of CMS’s Medicare Prescription Drug Benefit Manual describes behaviors that CMS considers to be potential fraud by manufacturers “*related to the Part D program*”—including “*inappropriate marketing and/or promotion of products . . . reimburseable by federal health care programs.*” *Id.* at 12 (emphasis added); *see also* 5/29/24 Tr. 4153:03–19, 4154:09–23 (Kaucher) (admitting that Janssen itself acknowledged CMS policy identifying potential fraud by manufacturer to include “*off-label marketing by a manufacturer*”) (emphasis added).
- Janssen further admitted that “Government enforcement against manufacturers allegedly engaged in the promotion of products for off-label uses *has been active and highly visible.*” DX2004 at 2 (“Guidance Document on the Promotion of FDA-Regulated Products”) (emphasis added).

Witness testimony from other fact and expert witnesses further confirmed these facts. For example:

- Relators’ compliance expert, Virginia Evans, testified that the government flatly “*does not cover the cost of prescription products*” when they have been provided in violation of the False Claims Act. 5/28/24 Tr. at 3762:5–11 (emphasis added). Pharmaceutical companies that disseminate OL information “in a promotional context” “violate

the False Claims Act” by promoting products for an indication for which it has not been approved or is not “medically necessary” or “reasonable and necessary.” *Id.* at 3796:01–23 (emphasis added).

- Evans further testified that, if the government pays for false claims under Medicare Part D and Medicaid without knowledge of their falsity, “***they will then go after and chase—and attempt to recoup that money.***” *Id.* at 3762:16–20, 3763:15–22 (emphasis added).
- Sara Strand testified that the federal government flatly “***would not pay***” for any claim that is the result of “***illegal off-label marketing***” and that, if such a claim had been paid, the federal government *would require the manufacturer to pay the money back to the government.* 5/09/24 Tr. at 905:06–12 (emphasis added).

Relators further presented extensive evidence that Janssen’s false and misleading promotion of Prezista and Intelence was illegal under federal law and caused physicians to write prescriptions that violated the standard of care for HIV patients and thus were potentially harmful.<sup>20</sup>

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<sup>20</sup> See 5/30/24 Tr. 4755:13–4757:23 (Patel) (testifying FDA regulations prohibit false and misleading marketing by a manufacturer, including omission of material facts or minimizing side effects); DX4263 (Patel-authored compliance document describing illegal OL promotion); 5/20/24 Tr. 2285:20–2286:9 (Glatt) (“FDA is supposed to protect all Americans from potentially dangerous medications . . . [a]nd the pharmaceutical industry is required, based upon the FDA rulings and regulations, to market their drugs only based upon the label.”), 2321:21–2322:1 (marketing Intelence to treatment-naïve patients is potentially dangerous), 2333:21–2334:15 (using Prezista for treatment-naïve patients prior to approval for that group had a “potential for harm”), 2414:8–2415:2, 2415:7–8, 2419:6–14 (Prezista lipid claim is misleading because Prezista’s label clearly lists adverse drug reactions of elevated cholesterol, elevated triglycerides and elevated bad cholesterol and “it clearly states . . . in the label, that this drug impacts in a negative way [a patient’s] lipids.”).

The totality of the evidence of the importance to the government of Janssen’s nationwide, false, and misleading promotion of Prezista and Intelence—and its likely effect on the payment decisions of federal and state government payors had they known—was overwhelming. The OL Prezista and Intelence prescriptions that Janssen caused to be submitted for reimbursement violated express conditions of payment. *See infra* Section I.C.2. Those requirements exist to prevent patient harm and fraud on the public fisc. Compliance with FDA laws prohibiting false and misleading or off-label marketing likewise protect patient safety and government funds. Violations of these laws by manufacturers, which CMS itself considers to be fraudulent, mean that the prescriptions are ineligible for reimbursement and the government will not pay. If the government learns of the violations after payment has been made, it will take action to chase the manufacturer and recoup its payment. And promotion of drugs consistent with product labels approved by the FDA, for uses that are proven safe and effective, is the “essence of the bargain” between manufacturers and the government payors from whom they seek reimbursement.

Finally, it would be unreasonable to claim that violations that caused damages to government payors of over \$150 million are minor or insubstantial. *United States ex rel. Streck v. Takeda Pharm. Am., Inc.*, 2023 WL 3093476, \*3 (N.D. Ill. Apr. 26, 2023) (denying defendant’s motions for judgment as a matter of law and for a new trial and finding materiality established where defendant’s FCA violations that

resulted in a jury verdict of \$61 million in damages to the government were not “minor or inconsequential”).

**2. There was no evidence that the Government had full knowledge of the fraud and agreed to continue to pay for the drugs.**

Janssen also argues that Relators do not have sufficient evidence of materiality because “the Government would have paid the claims with full knowledge of the alleged noncompliance.” Def. Br. at 18.<sup>21</sup> This argument is baseless and has no support in the record. It is also contradicted by the overwhelming evidence Relators produced and fails to consider that evidence in the light most favorable to Relators.

First, Janssen presented *no evidence* that the Government continued to reimburse prescriptions of Prezista and Intelence while having *actual knowledge* of Janssen’s OL marketing scheme. Janssen attempts to use the allegations and disclosures made *in this case* (and Ms. Graham’s later-filed case) to argue the Government knew of its fraudulent scheme. But knowledge of a relator’s *allegations* is not the same as full awareness of actual fraud. *See Care Alternatives*, 81 F.4th at

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<sup>21</sup> Janssen’s citation to *Petratos*, 855 F.3d 481, is easily distinguishable in that the *Petratos* relator conceded “that the Government would have paid the claims with full knowledge of the alleged noncompliance[.]” foreclosing any possible finding of materiality. *Id.* at 490. Here, Relators presented extensive evidence that the Government would not pay OL prescriptions of Prezista and Intelence. Similarly, *United States ex rel. Maur v. Hage-Korban*, 981 F.3d 516 (6th Cir. 2020), has no bearing on the issue of “materiality” under the FCA, as it discusses a completely unrelated provision of the FCA, the public disclosure bar, 31 U.S.C. § 3730(e)(4).

375 (“[W]e will not equate the government’s awareness of allegations of fraud with ‘actual knowledge’ that fraud occurred.”); *see also Escobar*, 842 F.3d at 112 (1st Cir.) (“mere awareness of allegations concerning non-compliance is different from knowledge of actual non-compliance”). Janssen’s argument would produce an illogical result—materiality would never be proven at trial in an FCA case because the FCA requires a relator to present their allegations and evidence to the government. *See* 31 U.S.C. §3730(b).<sup>22</sup> Regardless, Janssen presented this argument to the jury, which it unsurprisingly rejected.

Similarly unsupported, Janssen argues that it can be “assumed” that the government “would be aware” of the fraudulent promotion of Prezista and Intelence here based on the CIAs that provided for oversight by Independent Review Organizations (“IRO”). Def. Br. at 21–23. Janssen’s unfounded “assumption” is not enough to overturn a verdict against it as a matter of law. Moreover, the 2010 CIA *did not even exist* for the first five years of the Relevant Period. And good evidence of the fact that the 2010 CIA did not make the Government aware of Janssen’s OL promotion of other drugs within the J&J organization is the existence of *the 2013 CIA and Settlement Agreement* for illegal OL promotion of *yet other drugs*.

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<sup>22</sup> *See also* 6/10/24 Tr. 7443:19–7444:6 (THE COURT: “Is that your representation to the Court that in a False Claims Act allegation, if a whistleblower reports allegations to the government and payments continue, that that somehow equals the government deciding that . . . they don’t care that it’s not material to them? Because . . . this can’t be the only FCA case that’s ever existed in the United States.”).

Regardless, Janssen fails to cite to any evidence introduced to the jury whatsoever showing that the IRO or the Government was aware of Janssen's scheme involving Prezista or Intelence *in this case*. Considered in the light most favorable to *Relators*, Janssen's argument, untethered to the record, does not overcome the substantial evidence *Relators* presented on materiality.

**3. Janssen's other arguments are irrelevant to the FCA materiality analysis and must be rejected.**

Finally, contrary to Janssen's claims, the White House's policy of "unfettered access" to HIV drugs and CMS's recognition of antiretroviral drugs as one of six protected classes of drugs do not give it a "free pass" to commit massive healthcare fraud. Janssen's own documents recognize that there is *not* some sort of government exception for fraud because of these policies. *See* DX2069 (Janssen internal document recognizing the fraud and abuse risks for the six protected classes of drugs, including HIV medications). As the jury heard, Topamax and Risperdal, which are two of the drugs subject to the 2010 CIA and 2013 CIA and settlement, are included within the six protected classes of drugs. *See* 5/21/24 Tr. 2482:1–10. Janssen cites no caselaw in support of its argument that certain protected classes of drugs are outside the reach of the FCA and can therefore be illegally marketed.

None of Janssen's other arguments justify overturning the jury's finding as to materiality. For example, Janssen's assertion that the government would have paid

for an equally expensive alternative drug to Prezista and Intelence has no support in the record and, regardless, is irrelevant to materiality. Janssen's challenge fails.

**C. Relators Presented Substantial Evidence of Falsity**

Janssen next challenges the "falsity" element, contending that "Medicare does not bar coverage of the uses of Prezista and Intelence alleged in this case" and Relators "in any event failed to identify any specific false claim." Def. Br. at 24.

The jury was correctly instructed that "a claim made to a federal health care program is false if it seeks reimbursement for a prescription that is not eligible for reimbursement." *See* Dkt. 424-11 at 34 (Instruction No. 19.1, "Falsity"). The jury specifically found in Question One that Janssen's "*unlawful promotion*" of "Prezista *or* Intelence" violated the federal FCA. *See* Dkt. 435 at 2 (Verdict Form) (emphasis added). Janssen's Rule 50(b) challenge as to "falsity" fails if the evidence was sufficient to support the jury's verdict as to any one of the four promotional schemes alleged. Relators presented more than sufficient evidence that Janssen caused hundreds of thousands of claims to be submitted that were ineligible for reimbursement because all four of the illegal promotional campaigns violated at least one condition of payment, and the jury was entitled to find that Janssen caused the submission of false claims.

Relators first address the basis for liability that Janssen omits: that Janssen's "*unlawful promotion*," in violation of *FDA law* prohibiting that promotion, *itself*

caused the submission of claims that were not eligible for reimbursement. We then turn to the two separate, express conditions of payment set forth in the Court's instruction that Janssen's illegal conduct also violated: the "medically accepted indication" and "reasonable and necessary" provisions in the Court's Instruction No. 17. Janssen's illegal OL promotion violated all three conditions and therefore caused the submission of false claims that were "not eligible for reimbursement."

**1. Relators proved that Janssen's false and misleading OL promotions in violation of FDA law and regulations caused the submission of claims that violated a condition of reimbursement for federal healthcare programs.**

At trial, Relators proved through both fact witnesses and experts that Janssen orchestrated a top-down, nationwide, fraudulent scheme to market Prezista and Intelence to physicians OL. The evidence also demonstrated that Janssen intentionally minimized dangerous side effects (for example, the "serious adverse events" affecting lipids from Prezista) and promoted Prezista and Intelence for treatment-naïve patients and Intelence for once-daily dosing in order to increase sales and meet forecasts. Relators further proved that Janssen's OL marketing was false and misleading and violated FDA law—a *fact that Janssen does not even challenge in its Rule 50(b) motion*. And Relators proved that Janssen's unlawful promotion caused influenced physicians to write OL prescriptions for Prezista and Intelence. Finally, through extensive evidence at trial, Relators proved that compliance with FDA laws prohibiting false and misleading OL marketing like

Janssen engaged in here is *a condition of payment* for the government payors, and that Janssen is therefore liable because its illegal marketing caused the submission of claims for prescriptions that were “not eligible for reimbursement” pursuant to the Court’s jury instructions.<sup>23</sup> See Final Jury Instructions, Instruction No. 19.1 (“Falsity”). The evidence established that Janssen’s unlawful promotion caused physicians to write prescriptions for Prezista and Intelence that violated the standard of care for HIV patients and were potentially *dangerous*.<sup>24</sup>

The overwhelming evidence presented at trial demonstrated that Janssen not only knew that its false marketing was illegal but that the government *will not*

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<sup>23</sup> Janssen caused claims to be presented to federal and state health care programs that were false where the prescriptions were illegal or “misbranded in violation of the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 355(a) & (d).” See Dkt 315 at 82–83 (Final Pretrial Order). While the Court granted Janssen’s Motion in Limine under Rule 403 to preclude Relators from referring to the prescriptions at issue in this case as “misbranded” because those terms are unduly prejudicial, the Court fully recognized that Relators could still prove falsity at trial under the FDCA: “A jury finding that the prescriptions were in fact, illegal or misbranded, under the FCA is the ultimate finding Relators seek to receive in Count One.” See Dkt. 330 at 7 (MIL Opinion).

<sup>24</sup> Under the Food, Drug, and Cosmetic Act (“FDCA”), a drug is misbranded if its label is “false or misleading in any particular.” See 21 U.S.C. § 352(a). Any statements made about a drug by a pharmaceutical manufacturer such as Janssen are considered part of the drug’s labeling. See 21 U.S.C. § 321(n). It is plainly illegal, and a violation of the core tenet of the government’s regulation of pharmaceuticals, for a pharmaceutical manufacturer to introduce misbranded drugs into interstate commerce or take actions to misbrand drugs that are already in interstate commerce. See 21 U.S.C. §§ 331(a), (b); *Id.* at § 352(n); see Dkt. 86 at 12–13 (discussing the legal sufficiency of Relators’ FDCA allegations creating FCA liability).

*reimburse* for prescriptions that are caused to be submitted by a pharmaceutical manufacturer through false and misleading promotion that violates FDA law. *See supra* Section I.B.1. As the Supreme Court held in *Escobar*, liability under the FCA is not restricted only to a “violation of a contractual, statutory, or regulatory provision that the Government expressly designated a condition of payment.” 579 U.S. 176, 190 (2016) (“We conclude that the Act does not impose this limit on liability.”).

Rather, the FCA “imposes liability on those who present ‘false or fraudulent claims’ but *does not limit such claims to misrepresentations about express conditions of payment.*” *Id.* at 190–91 (emphasis added). Thus, “a defendant can have ‘actual knowledge’ that a condition is material without the Government expressly calling it a condition of payment.” *Id.* at 191; *see also United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh, Pennsylvania*, 728 Fed. Appx. 101, 106 (3d Cir. 2018) (“[E]ven though *Escobar* reaffirmed *Wilkins*’s holding that a defendant’s failure to comply with certain statutory, regulatory, or contractual requirements may violate the FCA, the Supreme Court made clear that those requirements *need not be express ‘conditions of payment’ to trigger FCA liability.* The Supreme Court determined that whether a defendant’s failure to comply with administrative regulations gives rise to liability requires a determination of whether

the defendant's non-compliance, if discovered, would have been 'material to the Government's payment decision.'") (emphasis added).

Relators' evidence at trial could not have been more on point to establish that compliance with FDA law and regulations against false and misleading OL promotion is a condition of payment by government payors. *See supra* Section I.B.1. The jury was thus entitled to find that (1) prescriptions written as a result of false and misleading promotion in violation of FDA law themselves violate a condition of reimbursement by government programs, and (2) Janssen therefore violated the FCA because its "*unlawful promotion*" caused physicians to write OL prescriptions of Prezista and Intelence that were ineligible for reimbursement. For this reason alone, Janssen's falsity challenge fails.

Moreover, as noted by the two Government Statements of Interest ("SOIs") filed in this case, "fraud that corrupts [a physician's prescribing] process by inducing physicians to prescribe a drug when they would not do so otherwise is actionable under the FCA." Dkt. 75 at 6 (noting that companies can be subject to FCA liability "for making false statements that induce a physician to prescribe a drug treatment paid for by the United States."); *see also* Dkt. 478 at 2 (stating "false statements that induce a physician to prescribe a particular drug can be actionable under the FCA even if the drug is prescribed for an FDA-approved indication"); *see also* Dkt. 291, at 17 (denying summary judgment and noting that "Relators point to evidence from

which a jury could conclude that Janssen's OL promotion of Prezista's lipid profile misled physicians"). Falsity for FCA liability may be established by identifying a scheme that corrupts doctors' exercise of their medical judgment because they relied on false information provided by the defendant. *See United States ex rel. Hinkle v. Caris Healthcare, L.P.*, No. 3:14-CV-212-TAV-HBG, 2017 WL 3670652 at \*2 (E.D. Tenn. May 30, 2017) (concluding "falsity" sufficiently pled in an FCA case because "physicians could not legitimately exercise their medical judgment because defendants provided false information on which the physicians relied.") (citation omitted).<sup>25</sup>

Here, the trial record demonstrated that Janssen's false and misleading marketing involved extensive and consistent efforts to mislead physicians regarding Prezista's lipid profile and approved patient population as well as Intelence's approved dosing and patient population. The jury was entitled to find that Janssen caused the submission of false claims as a result of its years-long, nationwide fraudulent marketing scheme directed at physicians. Janssen's challenge to falsity fails for this reason as well.

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<sup>25</sup> *See also Strom ex rel. U.S. v. Scios, Inc.*, 676 F. Supp. 2d 884, 891 n.2 (N.D. Cal. 2009) (where government alleged that Johnson & Johnson and its subsidiary, Scios, caused false claims to be submitted by fraudulently inducing thousands of doctors to submit claims for OL uses of a prescription drug that was not medically accepted for those uses, court held that defendants' misrepresentations deprived the physicians of the opportunity to "make considered medical judgments.").

**2. Relators *also* proved that certain alleged uses of Prezista<sup>26</sup> and Intelence were not for “medically accepted indications.”**

Janssen next argues that Relators “failed to proffer evidence” that any claim at issue was not “for a medically accepted indication.” Def. Br. at 24. This argument is meritless.

Separate and apart from Janssen’s violations of FDA law against false and misleading promotion of prescription drugs, Relators presented substantial, uncontested evidence at trial that prescriptions written for the uses of Prezista and Intelence at issue in this case were not for “medically accepted indications” and were, therefore, not reimbursable by the government payors. Federal law provides for this express condition of payment: Medicare will only pay for a drug that is used for a “medically accepted indication” which means any use that is approved by the FDA or supported by one of the specified compendia. 42 USC §§ 1396w-102(e), 1396r-8(k)(6).<sup>27</sup>

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<sup>26</sup> Janssen claims that “Relators’ principal assertion” is that use of Prezista in patients with a lipid condition “was not a medically accepted indication.” Def. Br. at 26. Janssen, of course, provides no pleading or record citation for this purported assertion by Relators because they never made such an assertion. *See* Dkt. 90 (Second Amended Complaint); Dkt. 351 (Relators’ Trial Brief); Dkt. 330 at 6–7, (MIL Opinion). Throughout the course of this litigation and at trial, Relators proved that prescribing Prezista for patients with a lipid condition is potentially harmful and is not medically necessary or reasonable given the availability of another drug, Reyataz, that did not have the same dangerous side-effects.

<sup>27</sup> In its brief, Janssen attempts to “preserve” its argument that Part D imposes no such “medically accepted indication” requirement. Def. Br. at 24 n.7. This is absurd, particularly because Janssen states on the prior page of its brief that “a prescription

In support, Relators presented lengthy and detailed testimony, including from Dr. Glatt—the only expert admitted expert on the standard of care for HIV and its application to Prezista and Intelence specifically—to address Janssen’s campaigns of illegal promotion, including: (1) Prezista for treatment-naïve patients; (2) Intelence for once-a-day (“QD”) dosing; and (3) Intelence for treatment-naïve patients. Through this evidence, Relators proved that Janssen’s illegal marketing caused prescriptions of Prezista and Intelence for treatment-naïve patients and Intelence for QD dosing that were not medically accepted because they were contrary to the indications on the FDA-approved label for those drugs and not supported in any compendia.<sup>28</sup>

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of a Part D drug is covered *as long as it is for a ‘medically accepted indication.’*” *Id.* at 23 (citing 42 U.S.C. §§ 1395w-102(e)(1) & (e)(3)(A)). Janssen cannot claim to preserve this issue now when it (1) failed to raise this issue in its Rule 50(a) argument at trial and it is therefore waived; and (2) it has actually taken the opposite position throughout this litigation, including in its 50(b) argument. *See* 6/10/24 Tr. 7434:20–7435:2 (stating Janssen’s counsel stated that Medicare Part D covers drugs prescribed for a “medically accepted indication”).

<sup>28</sup> *See* 5/20/24 Tr. 2329:24–2331:10 (Glatt) (testifying the 2006 Prezista label was “indicated” for patients with resistance to “two or more” protease inhibitors), 2333:17–20 (testifying the “recognized compendia” did not “support the use of Prezista in treatment-naïve patients” from 2006 to 2008), 2314:15–23 (testifying the Intelence label was “indicated” for a “very specific group of experienced patients” who “have to be resistant to an NNRTI” and “have resistance to other antiretroviral agents, which usually will mean a [protease inhibitor]”), 2318:8–19 (testifying the recognized drug compendia say the “[s]ame exact thing” as the guidelines and “do not recommend [Intelence] for treatment-naïve patients”), 2304:2–17 (testifying the Intelence label “indicate[s] that Intelence should be dosed” twice a day), 2307:9–13 (testifying the recognized compendia “say the exact same thing” as the DHHS and IAS guidelines, “that [Intelence] must be dosed twice a day”); *see also* Dkt. 424-11

Janssen’s own documents and witnesses admitted that promotion for different doses, dosing schedules, uses, patient population, or stage of disease constituted prohibited OL promotion of a drug. *See* RX360 at 59; *see also* 5/14/24 Tr. at 1369:25–1370:21 (Iacobellis).

Janssen now claims that a “medically accepted indication” refers to the “diagnosis or condition” for which a drug is prescribed but not “the dose” being prescribed. Def. Br. at 24. To make this argument, which pertains only to the Intelence QD dosing promotion, Janssen refers to a 2016 version of the Medicare Prescription Drug Benefit Manual referring to dosing but omits the following sentence: “Part D sponsors may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose restriction . . . based on medical necessity criteria.”<sup>29</sup>

Janssen introduced no evidence that QD dosing in violation of Intelence’s label requiring BID dosing was for a “medically accepted indication” and did not even argue this point to the jury. Its own former national sales director, Michael Iacobellis, admitted that prescribing Intelence for once-daily dosing was contrary to

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at 25 (Instruction No. 17, “Overview of Relators’ Claims”). Janssen does not argue that any of the OL uses of Prezista or Intelence at issue were referenced in any drug compendia.

<sup>29</sup> *See* Manual ch. 6 § 10.6 (issued, effective, and implemented in *January 2016*) (emphases added).

the drug's label and that messages promoting Intelence for QD dosing were "off-label" and would not be approved by the FDA. 05/14/24 Tr. 1461:1-21. The definition for "medically accepted indication" provided to the jury by the Court in its instructions was drawn directly from the statute, and Relators' evidence conformed to that statutory definition.

Moreover, for the Prezista and Intelence in treatment-naïve patients promotions, the FDA-approved labels for both drugs stated, in the "Indications and Usage" section, that the "safety and efficacy" of those drugs had not been established for treatment-naïve patients.<sup>30</sup> By definition, those drugs were not FDA-approved for use in treatment-naïve patients and any prescriptions for those patients would not be for a "medically accepted indication."

Janssen attempts to inject—yet again—the "Part D plan sponsor" into the equation, this time for the "falsity" element. It argues that Relators were required to introduce "evidence of final determinations on the coverage questions from Part D

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<sup>30</sup> See RX1148 at 14 (Prezista "Indications and Usage") (for "antiretroviral treatment-experienced adult patients, such as those with HIV-1 strains resistant to more than one protease inhibitor") (emphasis added); DX1045A at 2 (Intelence "Indications and Usage" 2008) ("for the treatment of HIV-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents") (emphasis added); DX4232 at 110 (Intelence "Indications and Usage" 2010) ("for the treatment of HIV-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 Strains resistant to an NNRTI and other antiretroviral agents") (emphasis added).

plan sponsors themselves” or expert testimony on that topic. Def. Br. at 24–25. As previously discussed in addressing Janssen’s causation arguments, above, proof of the Part D plan sponsors’ “final determinations” on coverage are not an element of an FCA violation and never have been.<sup>31</sup>

Moreover, under the FCA, Janssen is liable for causing false claims for payment to be presented to an agent of the United States *or* made to its contractor.<sup>32</sup> Janssen is therefore liable whether it was a substantial factor in causing false claims to be submitted *to* the Part D plan sponsors themselves *or* in causing the Part D plan

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<sup>31</sup> See Dkt. 291 at 15–16 (“In cases where a relator alleges the defendant caused the submission of false claims rather than submitting the claims itself, legal falsity nevertheless exists because the defendant ‘created and pursued a marketing scheme that it knew would, if successful, result in the submission by [others] of compliance certifications . . . that [the defendant] knew would be false.’”) (*citing United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004)).

<sup>32</sup> See *United States ex rel. Webb v. Miller Fam. Enter.*, No. 1:13-CV-00169-DBH, 2014 WL 6611012, at \*9 n.9 (D. Me. July 2, 2014) *report and recommendation adopted sub nom, Webb ex rel. United States v. Miller Fam. Enter.*, No. 1:13-CV-00169-DBH, 2014 WL 6611065 (D. Me. Nov. 20, 2014) (FCA liability attaches when a false claim is presented *to* a plan sponsor as a contractor for the government) (“Defendants have not provided reliable authority for the proposition that a false claim cannot be premised on a knowing violation of a contract provision simply because the contract is with a *plan sponsor* rather than a governmental agency. The mere presence of a private party intermediary does not insulate Defendants from potential FCA liability.”) (citing 31 U.S.C.A. § 3729(b)(2)(A)(ii)) (emphasis added); 31 U.S.C. § 3729(a)(1)(A) and (B) (FCA liability attaches for causing to be presented false claims or false records material to a false claim); *Id.* § (b)(2)(A)(ii) (defining “claim” to include those made to a contractor on government’s behalf for reimbursement from federal funds); *see also United States ex rel. Kester v. Novartis Pharmaceuticals Corp.*, 41 F. Supp. 3d 323, 337 (S.D.N.Y. 2014) (stating CMS contracts with Part D plan sponsors to administer prescription drug plans).

sponsors to submit claims to CMS.<sup>33</sup> The FCA does not require proof of the Part D plan sponsor's "coverage determinations" for any element, including falsity. Because the evidence was more than sufficient for the jury to determine that Janssen's illegal OL marketing was a substantial factor in causing the submission of false claims to CMS, its attempt to exploit an intermediary loophole fails.

Janssen attempts to save its "medically accepted indications" argument with an irrelevant discussion of the Eastern District of New York's decision in *Polansky*, 914 F. Supp. 2d 259 (2012); Def. Br. at 29-31. As discussed in the causation section, *see supra* Section I.A, that decision is wholly inapplicable to whether Janssen's unlawful promotion caused prescriptions to be written for indications that were not medically accepted. In *Polansky*, the labels for Lipitor included references to *guidelines* that were merely *advisory*, were not incorporated into the label, and had no bearing on whether the prescriptions were for medically accepted indications. *Id.* The prescriptions there were not OL prescriptions at all. Here, to the contrary—and as Dr. Glatt testified and Janssen did not even *contest* at trial—prescribing Intelence

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<sup>33</sup> See *United States ex rel. Buth v. Pharmerica Corp.*, No. 09-C-0720, 2014 WL 4355342 at \*6 (E.D. Wis. 2014) ("That the plan sponsors [rather than the defendant] filed the PDEs with CMS is irrelevant because liability attaches to any person who 'causes to be presented' a false or fraudulent claim.").

for once-daily dosing or Prezista and Intelence for treatment-naïve patients was directly contrary to the drugs' labels.<sup>34</sup>

Finally, Janssen resorts to policy argument and reference to national guidelines that have no bearing whatsoever on the fact that the illegally promoted uses of Prezista and Intelence in question were not for “medically accepted indications.” Def. Br. at 31-33. It also ignores the fact that Janssen induced thousands of doctors to write these prescriptions in *violation* of the national guidelines and standard of care for HIV patients, as Dr. Glatt testified.<sup>35</sup>

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<sup>34</sup> See also RX1148 at 14 (Prezista “Indications and Usage”) (for “antiretroviral treatment-experienced adult patients, such as those with HIV-1 strains resistant to more than one protease inhibitor”) (emphasis added); DX1045A at 2 (Intelence “Indications and Usage” 2008) (“for the treatment of HIV-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents”) (emphasis added); DX4232 at 110 (Intelence “Indications and Usage” 2010) (“for the treatment of HIV-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 Strains resistant to an NNRTI and other antiretroviral agents”) (emphasis added).

<sup>35</sup> See, e.g., 5/20/24 Tr. (Glatt) 2331:11–2333:16 (testifying the DHHS and IAS guidelines, which set forth the standard of care, stated that there was “insufficient data to recommend [Prezista’s] usage” in naïve patients), 2314:25–2315:15 (testifying the DHHS guidelines have “a strong statement” that Intelence “cannot be recommended as part of an initial therapy” and to “not use it . . . unless you meet the small niche population”), 2317:25–7 (testifying the IAS guidelines say the “[e]xact same thing as the DHHS guidelines,” that Intelence “should not be used in treatment-naïve patients”), 2305:24–2306:3 (testifying that the DHHS and IAS guidelines “both say the exact same thing, that [Intelence] [is] always recommended to be taken twice daily”).

There was substantial evidence for the jury to find that Janssen caused doctors to submit claims for uses of Prezista or Intelence that were not for “medically accepted indications”—an express condition of payment set forth in Instruction No. 17—and were therefore false claims because they were not eligible for reimbursement. Janssen’s challenge on this ground must be denied.

**3. Relators proved that the alleged uses of Prezista and Intelence were not “reasonable or necessary.”**

As provided by the law and consistent with the Final Jury Instructions, Medicare “[c]overage for drugs may . . . be excluded if they are not reasonable and necessary for the diagnosis or treatment of illness or injury.” *See* Dkt. 424-11 at 25 (Instruction No. 17, “Overview of Relators’ Claims”); *see also* 42 USC §§ 1395w-102(e)(3), 1395y(a)(1)(A). Relators’ evidence at trial clearly established the falsity of the claims for Prezista and Intelence because the alleged uses promoted by Janssen were not reasonable or necessary for the treatment of HIV patients.<sup>36</sup>

In their last gasp on the “falsity” element, Janssen makes two arguments, both of which are unavailing. First, Janssen contends that plan sponsors have discretion in deciding whether to apply the “reasonable and necessary” requirement and, thus, Relators needed to—yet failed—to prove that any plan sponsors would have “elected”

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<sup>36</sup> This Court has twice ruled that a party can prove a claim is legally false for purposes of the FCA by proving that the underlying prescription was not reasonable and necessary. *See* Dkt. 86 at 8-9; Dkt. 291 at 16.

to apply this requirement. Just as with its causation arguments, *see supra* Section I.A, Janssen provides no authority for this “Part D plan sponsor” proposition as to the falsity element.

Regardless, Relators introduced evidence at trial that CMS requires Part D plan sponsors to apply the medically “reasonable and necessary” standard as a condition of payment. *See* RX1188 at 1, 20 (“CMS Instructions: Requirements for Submitting Prescription Drug Event Data”) (“Except for smoking cessation drugs, ***Part D drugs must be prescribed for the purposes allowed under § 1862(a)*** and § 1927(d)(2) (*e.g., reasonable and necessary guidelines*, exclusion of drug classes used for weight loss or cosmetic surgery )”) (emphasis added); *see* Social Security Act § 1862(a), 42 U.S.C. § 1395y (“no payment may be made under part A or part B for any expenses incurred for items or services ... (1)(A) which, except for items and services described in a succeeding subparagraph, are not ***reasonable and necessary*** for the diagnosis or ***treatment of illness or injury*** or to improve the functioning of a malformed body member”) (emphasis added). Janssen introduced absolutely no evidence to the contrary. The jury was thus entitled to find that Part D plan sponsors would have followed those instructions and *would not have* approved prescriptions that are not medically reasonable and necessary per CMS’s directive.

Moreover, Janssen again fails to recognize that a claim is also false under the FCA when Janssen induced false claims to be submitted, *whether to or by the Part*

*D plan sponsor* as the contractor for the government.<sup>37</sup> *See supra* Section I.C.2 at 40. And in a case like this, that makes perfect sense. Where Janssen’s false and misleading marketing caused physicians to write medically unnecessary and unreasonable prescriptions for Prezista and Intelence, the fact of that illegal influence on the physician’s medical judgment is not even disclosed to the Part D plan sponsor or to CMS. In fact, as Janssen itself put into evidence and repeatedly argued at trial (presumably for another purpose), for HIV drugs and others in protected classes, Part D plan sponsors were not even permitted to use the drug utilization tools or quality assurance measures they are contractually required to leverage for all other drugs in order to discover whether the Prezista or Intelence prescriptions were medically reasonable or necessary. *See* Tr. 825:24-830:17 (Strand) (CMS prohibiting use of utilization management tools for HIV drugs); DX8606.

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<sup>37</sup> *See Buth*, 2014 WL 4355342 at \*6 (“That the plan sponsors filed the [prescription drug events] with CMS is irrelevant because liability attaches to any person who “causes to be presented” a false or fraudulent claim. The United States is not contending that the plan sponsor knowingly presented the false claim but rather that [defendant] knowingly ‘caused the claim’ to be presented *by the plan sponsor* who then sought payment from the government. Such allegations comport with the statutory language and are supported by case law holding a subcontractor liable under the FCA for causing a subcontractor to submit claims seeking payment for materials that—*unbeknownst to the contractor*—were labeled incorrectly.”) (emphasis added).

Instead, as the jury heard, the Part D program is “trust-based” and the Part D sponsors, facing a “fire hose” of claims for the government to pay within a short period of time, might approve claims while being unaware that the prescriptions for the drugs in question are not reasonable and necessary or otherwise violate the FCA. *See* Tr. 3762:05–3763:22 (Evans). Where the government later learns that the claims submitted were false, it will “chase” the manufacturer and seek to recoup the monies it reimbursed. *Id.* The jury was entitled to infer, based on the evidence presented at trial, that the nature of the fraudulent conduct by Janssen here deprived the Part D plan sponsors and CMS of the ability to determine whether the claims for Prezista and Intelence were reasonable and necessary to begin with.

More importantly, the jury was entitled to conclude—based on the availability of other drugs, the violations of the standard of care, the potential for patient harm attested to by Dr. Glatt, and the government payors’ *policies against false and misleading marketing* by a manufacturer—that even if the decision to cover a drug that is not “reasonable and necessary” were in the discretion of the plan sponsors, they *would not have* approved the claims for payment had they known of Janssen’s fraudulent conduct. As the factfinder, the jury was entitled to make these determinations.

Janssen next argues that Relators failed to prove that any prescription was not “reasonable and necessary” for the “individual patient” based on “accepted standards

of medical practice and the medical circumstances of the individual case.” Def. Br. at 35 (citing *Petratos*, 855 F.3d at 488). Janssen has consistently misconstrued the holding of *Petratos* and this Court has, at every stage, rejected Janssen’s interpretation that it requires individualized patient-by-patient level of proof. *See* Dkt. 291 at 17–19 (Sum. Judgment Op.); *see also* Dkt. 86 at 9 (Mot. to Dismiss Op.).

The Third Circuit in *Petratos* found that the statutory “medically accepted indication” and “reasonable and necessary” conditions were separate and distinct, disagreeing with the district court’s conclusion that they were coterminous. 855 F.3d at 487–88. In so holding, the court specifically found that a drug could be prescribed for a “medically accepted indication” but still not be “reasonable and necessary” based on “standard medical practice.” *Id.* at 488. Thus, physicians play an important role in determining whether a prescription is “reasonable and necessary” for a patient. That holding certainly does not help Janssen.

The facts of this case demonstrated that Janssen’s false and misleading marketing, persistent and pervasive to more than 5,000 influenced HIV doctors, affected doctors’ medical judgment, leading to rates of OL prescribing of Prezista and Intelence that were far in excess of non-influenced physicians. The testimony from Dr. Glatt established that the OL prescriptions from these physicians for Prezista and Intelence, and the prescriptions for Prezista for patients with lipid issues, *violated the standard of care for those HIV patients* and could have subjected

patients to *cardiac injuries*.<sup>38</sup> The jury was entitled to find that Janssen caused doctors to submit prescriptions of Prezista or Intelence for reimbursement that were not medically reasonable or necessary for those patients or uses—particularly given the availability of alternative drugs.

Dr. Glatt’s testimony was not controverted by *any expert* proffered by Janssen.<sup>39</sup> Nothing in *Petratos* holds that, for the nationwide fraudulent marketing scheme perpetrated by Janssen in this case, only individualized *proof* across hundreds of thousands of prescriptions would suffice for Relators to prove their claims. Instead, the jury was entitled to credit Dr. Glatt’s testimony regarding the standard of care for the treatment of all HIV patients by all physicians, together with the extensive evidence of the effects of Janssen’s marketing, the claims data for CMS and ADAP, and the statistical evidence of physicians’ prescribing behavior, and

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<sup>38</sup> See 5/21/24 Tr. 2447:3–7 (Glatt) (testifying that prescribing Prezista to “lipid-impacted HIV patients” would “violate the standard of care”); see also 5/20/24 Tr. 2313:10–14 (testifying that prescribing Intelence “once a day” would violate the “accepted standard of care”), 2324:3–6 (testifying that prescribing Intelence “in treatment-naïve patients” would “[c]ertainly” violate “the prevailing standard of care”), 2333:5–10 (testifying that, between 2006 and 2008, prescribing “Prezista in naïve patients” would violate the “standard of care”), 2433:20–2434:12 (testifying regarding published study in 2017 “that specifically shows that outcome of cardiac events, no longer lipid problems, but the *cardiac injuries* were higher in the Prezista group than in the Reyataz group.”).

<sup>39</sup> *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 100–1 (3d Cir. 2020) (holding that falsity can be established through an expert’s testimony).

conclude that certain prescriptions for Prezista or Intelence were not medically reasonable or necessary.

While Janssen points to some evidence at trial that it believes undermined Relators' claims, *see* Def. Br. at 35–36, that is *jury argument* again. The jury was entitled to credit or discredit the uncontroverted testimony of Relators' expert, Dr. Glatt, or of certain influenced physicians called by Janssen, and render its verdict—which is exactly what it did.

Janssen's Rule 50(b) challenge based on the “reasonable and necessary” requirement fails.

**4. Relators identified hundreds of thousands of false claims.**

Finally, Janssen argues that Relators did not provide evidence of “at least one false claim” submitted for payment to CMS. Def. Br. at 37. This argument is meritless.

Relators introduced the entirety of the CMS claims data (for Medicaid Part D claims and Medicaid claims) and ADAP claims data at issue in this case as exhibits through data expert Ian Dew. The exhibits containing the data from those databases and specific pharmacies were admitted into the record without objection.<sup>40</sup> Dew described in detail the data that he gathered, including “claims submitted to

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<sup>40</sup> *See* 5/31/24 Tr. 5223:24–5224:18; RX1480 (“CMS claims data”); DX5005 (“ADAP data”); RX487 (“data from BioScrip”); DX5009 (“RiteAid data”); RX1003 (“Walgreens-related data”).

government healthcare programs, in particular, pharmacy claims for Prezista and Intelence.” *See* 5/31/24 Tr. 5221:21–5222:04. He analyzed 88 million Part D “prescription drug event” (“PDE”) records for the claims in this case and 226 million Medicaid claims.<sup>41</sup> *Id.* at 5225:18–25. Dew received all ADAP data in aggregate form for claims by drug and state for 2008 through 2014. *Id.* at 5226:06–16. Shaked then attested to the number of false claims and damages based upon the data analyzed and summarized by Dew. *See* Tr. 5410:12–5411:05.

Given the actual claims data in the record, attested to by an expert in data analysis in FCA cases and a statistics and damages expert who relied on that data, Janssen’s vague assertion that Relators did not provide evidence of a “single false claim” is baseless.

Janssen’s Rule 50(b) challenge as to falsity should be denied.

## **II. RELATORS PROVED THEIR “STATE-LAW” CLAIMS**

Janssen next argues that Relators (1) “failed to establish the coverage requirements” for ADAP and state Medicaid plans; and (2) “failed to prove the elements of any of their claims as to these programs.” Def. Br. at 38. Because the

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<sup>41</sup> *See Buth*, 2014 WL 4355342 at \*6 (“Essentially, each PDE submitted to CMS is a summary record documenting the final adjudication of a dispensing event based upon *claims* received from pharmacies and the data in PDEs are data related to the payment of claims.”) (emphasis added).

record contained sufficient evidence to support the jury's findings, Janssen's Rule 50(b) challenge fails here too.

**A. Relators Proved That the OL Prezista and Intelence Prescriptions were Ineligible for Reimbursement by ADAP and Medicaid.**

The jury was instructed on the elements of the federal FCA. *See* Dkt. 424-11 at 33–37 (Instruction Nos. 19–19.4). The Court further instructed the jury that those elements likewise apply to the States' FCAs (with the exception of Texas, for which the jury was provided separate instructions). *See* Dkt. 424-11 at 42–43 (Instruction No. 23, “State Law Claims”). The jury was specifically instructed that the state-law claims apply only to *state Medicaid programs* and that, if the jury found that Janssen violated the federal FCA, it must also find that Janssen violated the state-law analogs. *Id.*<sup>42</sup>

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<sup>42</sup> Janssen improperly includes Relators' ADAP claims in its “state-law claims” challenge. ADAP is a federally funded program. *See AIDS Healthcare Foundation, Inc. v. Okaloosa AIDS Support and Informational Services, Inc.*, No. 4:23CV230-MW/MAF, 2023 WL 11926188 at \*1 (N.D. Fl. Oct. 10, 2023) (“Under the Ryan White Program, the federal government, through the Department of Health and Human Services (HHS), provides grants to state governments for services—including medical care, case management, and prescription funding—to low-income individuals living with HIV/AIDS.”); *United States v. AIDS Healthcare Foundation, Inc.*, No. 14-CV-61301-KMW, 2016 WL 11783286 at \*3, n.8 (S.D. Fl. July 19, 2016) (“The Ryan White CARE Act, 42 U.S.C. § 300ff *et seq.*, as amended, establishes a grant program administered by two divisions of the Department of Health and Human Resources (‘HHS’): the Health Resources and Services Administration (‘HRSA’) and the Centers for Disease Control and Prevention (‘CDC’). HRSA and CDC provide federal funds to community-based organizations, either directly or indirectly, through State or local agencies, for programs designed to expand medical care for people living with HIV/AIDS and to increase awareness

These instructions were correct. *See* Dkt. 424-1 at 79–80 (Parties’ Jointly Proposed Jury Instructions). As Janssen itself acknowledges, federal and state FCA claims “succeed or fail together” where “no party has alleged a material difference between the standards applicable to the FCA and equivalent state laws.” Def. Br. at 42 (*citing United States ex rel. Travis v. Gilead Scis., Inc.*, 596 F. Supp. 3d 522, 543 n. 159 (E.D. Pa. 2022)); *see also United States ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 322 (D.N.J. 2015). Because the record was more than sufficient for the jury to find that Janssen’s unlawful promotion violated the federal FCA, Janssen’s challenge to the “state-law” claims fails.

First, ample evidence at trial, *see supra* Section I.B.1, established that compliance with FDA laws prohibiting manufacturers’ false and misleading promotion of drugs—which caused prescriptions that violated that standard of care for HIV patients and were potentially harmful—was a condition of reimbursement for *all the government payors* in this case. Janssen’s false and misleading promotion of Prezista and Intelence therefore caused physicians to submit claims for payment to ADAP and state Medicaid plans that were not eligible for reimbursement. *See supra* Section I.A. The evidence further established that Janssen’s unlawful

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of HIV status.”). Relators address Janssen’s ADAP arguments here for ease of reference only.

promotion was material to the government payors. *See supra* Section I.B. Janssen’s challenge to Relators’ ADAP and Medicaid claims fail for these reasons alone.

Janssen’s challenge to the “state-law” claims skips this point entirely and proceeds directly to express “conditions of payment” for the state Medicaid and ADAP programs. Def. Br. at 38. It argues that “Relators failed even to *identify* the requirements of these programs, much less *prove* them[.]” *Id.* (emphasis in original). That argument is unfounded.<sup>43</sup>

The Court instructed the jury on certain express conditions of payment for Medicare Part D, Medicaid, and ADAP programs depending on whether the drugs are prescribed for a “medically accepted indication” or are medically “reasonable and necessary.” *See* Dkt. 424-11 at 25 (Instruction No. 17, “Overview of Relators’ Claims”). It further instructed the jury that a claim made to a federal health care program is false if it seeks reimbursement for a prescription that is not eligible for reimbursement.” *Id.*, at 34 (Instruction No. 19.1, “Falsity”).

Ignoring the evidence Relators presented in conformity with these instructions, Janssen argues that state Medicaid programs “*may* exclude or otherwise

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<sup>43</sup> Janssen’s repeated arguments that Relators had a burden to “prove” an instruction that the Court provided the jury on express conditions of payment for Medicare, Medicaid, and ADAP is not only wrong, it is intentionally wrong—and Janssen has waived any objections to the Court’s jury instructions on coverage requirements. *See* Relators’ Brief in Opposition to Janssen’s Motion for New Trial, filed contemporaneously, which Relators incorporate herein by reference.

restrict coverage” of a drug because the prescribed use is not for a “medically accepted indication” and that ADAP imposes “no restriction on off-label uses of HIV drugs[.]” Def. Br. at 39 (emphasis in original). Thus, Janssen contends that Relators failed to make a “showing” that the statutory requirements of either program rendered the prescriptions for Prezista and Intelence false. *Id.* at 40.

At the outset, Janssen’s assessment of the express conditions of payment for the States’ Medicaid programs and ADAP are incorrect. *See Polansky*, 822 F.3d at 615 (“Federal reimbursement for prescription drugs under Medicare and Medicaid is generally limited to drugs prescribed for FDA-approved (on-label) uses or for certain purposes included in any of three drug compendia.”). Moreover, every one of the states at issue in the case requires, as a condition of reimbursement, that a prescription be “medically necessary” for the patient.<sup>44</sup> And contrary to Janssen’s

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<sup>44</sup> *See* Exhibit B, attached hereto, referencing applicable state authority. *See also United States ex rel. Gardner v. Vanda Pharmaceuticals, Inc.*, 554 F. Supp. 3d 146, 159, 161 (D.D.C. 2021) (“Most, if not all, State Medicaid programs exclude coverage for drugs that are used for off-label indications that are not medically accepted. Such use can waste Medicaid funds on ineffective treatments.”) (quoting CMS policy document, “Off-Label Pharmaceutical Marketing: How to Recognize and Report It,” available at <https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaid-integrity-education/downloads/off-label-marketing-factsheet.pdf>, demonstrating that on-label use for medically accepted indications is a “condition of payment under Medicaid”)

assertions, ADAP will not cover claims for prescription drugs that are not for “medically accepted indications” or are not medically necessary.<sup>45</sup>

Moreover, the evidence before the jury demonstrated that *Janssen itself knew* that government health care programs *do not cover* prescriptions caused by OL marketing that are not proven “safe and effective” by the FDA, are not prescribed

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<sup>45</sup> See Ryan White HIV/AIDS Program, AIDS Drug Assistance Program (ADAP) Manual, at 9, 13, 44, <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/adap-manual.pdf> (stating ADAP recipients must comply with “federal grant requirements as found in” 45 C.F.R. § 75.403(a) and 2 C.F.R. § 200.403(a), “must ensure” patients are treated “consistent with the current HHS treatment guidelines,” must “acquire drugs ‘in the most economic manner feasible’” as in 42 C.F.R. 50.504 and 42 U.S.C. § 256b, and excluding drugs from coverage “used when there is no medically accepted indication” and incorporating by reference the Medicaid Statute, 42 U.S.C. § 1396r-8(k)(2)); see also Ryan White HIV/AIDS Program, AIDS Drug Assistance Program (ADAP) Manual, at 7, 12, 50, <https://targethiv.org/sites/default/files/file-upload/resources/ADAP%20Manual%203-15-2016.pdf> (same); see also Ryan White HIV/AIDS Bureau, Division of State HIV/AIDS Programs, AIDS Drug Assistance Program (ADAP) Manual, at 7, 20, 83–85, <https://www.govinfo.gov/content/pkg/GOVPUB-HE20-PURL-gpo60655/pdf/GOVPUB-HE20-PURL-gpo60655.pdf> (same); see also Ryan White HIV/AIDS Program, Clarifications Regarding Medicaid-Eligible Clients and Coverage of Services, Policy Clarification Notice (PCN) #13-01, at 3 (revised Dec. 13, 2013), <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/1301-pcn-medicare-eligible.pdf> (stating ADAP “funds may be used to pay for any *medically necessary* services which Medicaid does not cover or only partially covers”), see also Ryan White HIV/AIDS Program, Frequently Asked Questions – Policy Clarification Notices (PCNs) 15-03 and 15-04, at 5 (March 21, 2016), <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/faq-15-03-15-04.pdf> (same); see also Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds, Policy Clarification Notice (PCN) #16-02 (Oct. 22, 2018), <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/service-category-pcn-16-02-final.pdf> (stating costs charged to ADAP funds “must be necessary and reasonable”).

for “medically accepted indications,” or are the product of “false and misleading statements about the safety and efficacy” of a drug. RX1486 at 2–4 (including Medicare, Medicaid, and other federal healthcare programs); *see also* 5/23/4 Tr. 3762:05–16 (Evans) (government payors include Medicare and Medicaid), 3796:01–24 (government will not pay for “medically unnecessary” drugs or drugs that are not “reasonable and necessary” by rule); 3812:04–3813:19 (discussing Janssen settlement for OL marketing of other drugs in violation of Medicare and Medicaid conditions of payment), 3819:13–3824:05 (same); *see also supra* Section I.C.2–3.

Relators’ expert, Dr. Glatt, testified extensively regarding the medically accepted indications for Prezista and Intelence, the requirements that prescribed drugs be proven safe and effective, the standard of care for HIV patients, and the potential for patient harm as a consequence of the prescriptions for Prezista and Intelence caused by Janssen’s unlawful promotion. *See, e.g., supra* Section I.C.3 at 47–48. Based on the totality of the evidence presented at trial, the jury was entitled to find that Janssen’s unlawful promotion caused claims to be submitted to ADAP and state Medicaid programs that were “not eligible for reimbursement” and that the government payors would have found Janssen’s unlawful conduct material in denying coverage had they known of the violations.

Taking the evidence in the light most favorable to Relators, Janssen’s “state-law” challenges based on an alleged failure of proof regarding “conditions of payment” must be denied.<sup>46</sup>

### **III. THE EVIDENCE SUPPORTS THE VERDICT AND THE NUMBER OF CLAIMS**

#### **A. The Court Applied The Correct Measure of Damages And The Jury’s Verdict Comports With The Evidence And The Instruction**

Janssen next attacks the jury’s findings as to the number of false claims and damages. As to damages, the jury was properly instructed that “[t]he measure of damages under the False Claims Act is the amount of money that the Government paid out by reason of the false claims.” Dkt. 424-11 at 46 (Instruction No. 26 “Measure of Damages”). Janssen argues that this instruction was erroneous and it is entitled to judgment because the Court should have applied the “benefit of the bargain” measure of damages to this case. Def. Br. at 43–46, n.28. Janssen’s argument should be rejected because (1) Janssen misstates the law; and (2) Janssen presented no evidence regarding the measure of damages it contends is correct—“the difference in cost between that contracted for and that received.” *Id.* at 43.

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<sup>46</sup> Janssen also makes the sweeping contention that Relators’ ADAP and state Medicaid claims fail for the same reasons that their Medicare claims allegedly fail. Def. Br. at 42. To the contrary, Janssen’s challenges fail because Relators adduced far more than sufficient evidence at trial on causation, materiality, and falsity with respect to the Medicare claims. *See supra* Sections I.A, B, and C.

Contrary to Janssen’s argument, Relators proved the government is entitled to the full amount that it paid for OL claims that were ineligible for reimbursement.

First, Janssen is wrong on the law. Benefit of the bargain is *not* the “general rule” of damages that must be applied in this case. Def. Br. at 43–46. In fact, there is no specific formula for determining FCA damages, and courts fashion damages on a case-by-case basis so that the Government is “be afforded a full and complete recovery of all its damages.”<sup>47</sup>

In health care fraud cases like this one, it is well settled that courts award the government the full amounts that it paid out on false claims that were ineligible for reimbursement, routinely rejecting the “benefit of the bargain” measure of damages.<sup>48</sup> This is because the government did not directly receive any prescription drugs. Under the health care subsidy programs Medicare, ADAP, and Medicaid, the

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<sup>47</sup> S. Rep. No. 96-615 at 4 (1980) (reporting on S.1981, predecessor to S.1562). The legislative history of the FCA makes it clear that there is no specific formula for FCA damages: “No single rule can be, or should be, stated for the determination of damages under the Act . . . [T]he courts should remain free to fashion measures of damages on a case-by-case basis. The Committee intends that the courts should be guided only by the principles that the United States’ damages should be liberally measured to effectuate the remedial purposes of the Act, and that the United States should be afforded a full and complete recovery of all its damages.” *Id.*

<sup>48</sup> See *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (holding, in Medicare and Medicaid fraud case where “[t]he government offers a subsidy . . . with conditions” and “the conditions are not satisfied, nothing is due” and “the entire amount that [the defendant] received” for the false claims “must be paid back”); *United States v. Mackby*, 339 F.3d 1013, 1018 (9th Cir. 2003); see also *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015).

government payors cover the costs of drugs for program beneficiaries who receive the value of those drugs.

Here, the record is undisputed: Janssen provided Prezista and Intelence to HIV patients and the cost of the drugs was reimbursed by the government payors. As the Government received no direct benefit, the proper measure of damages was applied here. The Government is entitled to the full value of Prezista and Intelence prescriptions incurred by reason of Janssen's OL marketing scheme that were ineligible for reimbursement.<sup>49</sup>

Second, Janssen's argument is a thinly veiled attempt at a setoff defense, which it did not plead. *See* Dkt. 315 (Final Pretrial Order). While Janssen claimed that its damages expert, Jena, had "deductions" from the Government's damages to account for the "benefit of the bargain," (*Id.* at 48), Janssen failed to present any such evidence to the jury. *See* 6/10/24 Tr. 7643:03–7645:13 (Jena) (admitting that Janssen presented no alternative damages calculation to the jury). Thus, Janssen cannot make this challenge now. *See United States ex rel. Drakeford v. Tuomey*, 792

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<sup>49</sup> *See, e.g., United States ex rel. Lutz v. BlueWave Healthcare Consultants, Inc.*, No. 9:11-CV-1593-RMG, 2018 WL 11282049, at \*1–3 (D.S.C. May 23, 2018), *aff'd sub nom. United States v. Mallory*, 988 F.3d 730 (4th Cir. 2021) (upholding jury's damages verdict for the full value of the medically unnecessary false claims); *see also United States v. Robinson*, No. CV 13-27-GFVT, 2016 WL 7030447, at \*5–7 (E.D. Ky. July 8, 2016) *aff'd*, 705 Fed. App'x. 458 (6<sup>th</sup> Cir. 2017) (denying motion for new trial where jury awarded government full value of all of defendant's optometry claims it determined were medically unnecessary).

F. 3d 364, 385 (4th Cir. 2015) (court rejected the defendant’s challenge to the jury’s damage award where “Tuomey was entitled to offer its own expert and its own alternative damage calculation, but elected not to do so”).<sup>50</sup>

For these reasons, Janssen’s arguments regarding “benefit of the bargain” damages should be rejected.

**B. Relators’ Damages Model is Supported by the Evidence**

Janssen next argues that Relators failed to prove damages and the number of false claims “because the evidence they proffered was unreliable and lacked factual basis.” Def. Br. at 46. In support thereof, Janssen simply refers to its previously-filed motion to strike Relators’ experts Shaked and Ian Dew, *which this Court already denied*, and asserts that these experts’ calculations relied on unproven factual assumptions. Janssen says that no jury could accept these experts’ calculations, and Relators had no admissible evidence on damages. *Id.* at 47.

This is the *third time* that Janssen has posed these arguments aimed at Shaked and Ian Dew (first in its *Daubert* motion, and then again in its Motion to Strike these experts filed during trial), which this Court has already rejected twice. *See* Dkt 294

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<sup>50</sup> Even if offsets were available for health care fraud damages, any such value to the government that Janssen could prove (but did not) would only be deducted from FCA damages *after trebling*. Per the United States Supreme Court: “[I]n computing the double [now treble] damages authorized by the [False Claims] Act, the Government’s actual damages are to be doubled [now trebled] before any subtractions are made for compensatory payments previously received by the Government from any source.” *United States v. Bornstein*, 423 U.S. 303, 316 (1976).

at 31–37; 6/10/24 Tr. at 7748:16–7749:23, 7753:12–16. For the sake of brevity, Relators refer the Court to all of their arguments made in their prior Opposition to Janssen’s Motion to Strike these experts, filed on June 11, 2024 (Dkt 408).<sup>51</sup> For all the same reasons, and as the Court has already ruled before, the Court should again reject Janssen’s arguments here.

**C. The Jury’s Findings On The Number Of False Claims And The Amount Of Damages Is Supported By Substantial Evidence**

Janssen next baldly asserts that the jury’s assessment of the number of false claims and damages are “arbitrary” and “lack evidentiary support” because they differ from the total number of false claims and the global amount of damages to government payors calculated by Professor Shaked.<sup>52</sup> But the notion that a jury must accept a plaintiff’s proffered evidence of false claims and damages *in toto*, or else

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<sup>51</sup> Other than referring to its previously denied motion to strike these experts, Janssen asserts that two minor issues in the pharmacy data considered by Ian Dew rendered the experts’ opinions unreliable. *See* Def. Br. at 47. Janssen does not explain how these data issued impacted the experts’ opinions. Further, this pharmacy data *only* relates to determining the percentage of OL Intelence once-daily dosing prescriptions and has no bearing on any of the other opinions offered by these experts. *See* 5/31/24 Tr. at 5226:20–5227:7. At trial, Mr. Dew testified that the pharmacy data contained 302,000 data points that allowed him to make very accurate estimates. *See* 5/31/24 Tr. at 5318:1–5319:16, 5323:22–25. The jury was permitted to weigh Mr. Dew’s testimony on these points.

<sup>52</sup> Janssen contends it is “clear” that the jury “rejected” the damages model offered by Relators’ expert, Professor Shaked, (Def. Br. pp. 47-48), but does not explain how the jury’s findings evince any such “rejection” other than that the jury’s final calculations differ from Shaked’s global totals for false claims and damages.

its findings will be disregarded, ignores the factfinder's role in weighing the evidence and inverts the applicable legal standard when deciding a motion for judgment as a matter of law.

The task of determining the number of false claims submitted under the FCA and the amount of damages for which Janssen is liable under the federal and state FCAs was within the sole province of the jury. District courts in the Third Circuit are required to “uphold the jury’s award if there exists a reasonable basis to do so.” *Ford Motor Co. v. Summit Motor Products, Inc.*, 930 F.2d 277, 290 (3d Cir. 1991) (quoting *Motter v. Everest & Jennings, Inc.*, 883 F.2d 1223, 1230 (3d Cir.1989)). A jury’s damages verdict “must be upheld so long as it is supported by a ‘minimum quantity of evidence from which a jury might reasonably [decline to] afford relief.’” *Arnold’s Office Furniture, LLC v. Borden*, No. 5:20-CV-05470-JMG, 2023 WL 3851978 at \*6 (E.D. Pa. June 6, 2023) (quoting *Ansbro v. Nat’l R. R. Passenger Corp.*, No. CIV. A. 90-5042, 1991 WL 258831 at \*1 (E.D. Pa. Dec. 3, 1991)); see *Ford Motor Co.*, 930 F.2d at 290.<sup>53</sup>

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<sup>53</sup> A trial judge “must be extremely reluctant to interfere with the time-honored power of the jury, in the exercise of its collective judgment, to assess the damages sustained by the plaintiff.” *Arnold’s Office Furniture*, 2023 WL 3851978, at \*6 (declining to speculate “on how the jury arrived at their damages award”); see *New Mkt. Inv. Corp. v. Fireman’s Fund Ins. Co.*, 774 F. Supp. 909, 917 (E.D. Pa. 1991) (“The mere fact that neither the plaintiff nor the Court has been able to mathematically deduce how the jury arrived a[t] such a figure does not mandate that the jury’s verdict should be overturned or a new trial awarded by this Court.”).

Janssen ignores these standards and the deference afforded the factfinder in assessing the number of false claims and damages. And, while acknowledging up front that a Rule 50(b) motion for judgment as a matter of law “requires that ‘the court . . . review *all* the evidence in the record,’” Def. Br. at 5–6 (emphasis added), Janssen instead points to only a fraction of the evidence the jury had at its disposal in rendering its verdict: namely, the total number of false claims and the global damages to government payors that Shaked estimated and the top-level breakdown of damages by the four categories of Janssen’s unlawful promotion of Prezista and Intelence. *Id.* at 48. Missing from Janssen’s cursory summation are the myriad component parts of Shaked’s analysis,<sup>54</sup> competing testimony from Janssen’s own expert, the underlying documentary evidence and testimony of more than 25 fact and expert witnesses, and the basic recognition that the jury, as factfinder, was entitled to weigh and credit any or all of that evidence in arriving at its findings of the number of false claims and the amount of damages.<sup>55</sup>

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<sup>54</sup> The demonstrative slide deck used to present Shaked’s testimony is attached as Exhibit A-1 (“Shaked Demo”).

<sup>55</sup> *See* Dkt. 424-11 at 45 (Instruction No. 25, “Damages – Overview”) (“Relators *are not required to prove the exact amount of damages*, but Relators must show sufficient facts and circumstances to permit you to make a reasonable estimate of the damages.”) (emphasis added).

For instance, the jury found that Janssen violated the federal FCA by unlawfully promoting “Prezista or Intelence.” *See* Dkt. 435 at 2 (Verdict Form). The jury was entitled to find that Relators proved all, some, or none of the alleged false claims that Janssen caused to be submitted and the damages resulting from its unlawful promotion of (1) Prezista for naïve patients (\$1.9M), (2) Prezista for those with a lipid condition (\$414.3M), (3) Intelence for naïve patients (\$16.4M), or (4) Intelence for once-daily dosing (\$32.4M). *See* 6/3/24 Tr. 5487–88; *see also* Shaked Demo. at 74.

Shaked further broke down the damages estimates for each of the four specific OL promotions by government payor, which Janssen’s own expert, Jena, himself acknowledged and purported to “correct.” *See* 6/10/24 Tr. 7617:11–7621:12.<sup>56</sup> The jury was entitled to find that each of Medicare, ADAP, or state Medicaid payors suffered all, some, or none of the damages allegedly resulting from any or all of Janssen’s four OL promotion schemes.

According to Jena, for instance, the ADAP data and certain extrapolations performed by Shaked were not sufficiently reliable. *See, e.g.*, 6/7/24 Tr. 7316–22. Shaked disagreed. *See, e.g.*, 6/3/24 Tr. 5579–81. Janssen argued in closing that the

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<sup>56</sup> Janssen’s own documents reflected its assessment of the payor mix for both Prezista and Intelence. *See, e.g.*, RX 1789 at 35–36.

ADAP data was entirely inadequate to support Relators' request for damages suffered by the ADAP program. *See* 6/11/24 Tr. 8091–92.

In the same vein, Shaked presented evidence demonstrating that the OL prescribing rates of influenced physicians were, on average, almost precisely double the OL prescribing rates of non-influenced physicians. *See* 6/3/24 Tr. 5449:04–5450:15;<sup>57</sup> *see also* Exhibit A-1 at 38 (Shaked Demo). Moreover, speakers alone accounted for 20 percent of all OL prescriptions during the Relevant Period for Prezista and Intelence reimbursed by all three government payors. *See* 6/3/24 Tr. 5459-60; *see also* Exhibit A-1 at 50 (Shaked Demo).

Further still, Shaked set forth, in total numbers and percentages, the multiple groups of influenced physicians based on their respective marketing contacts by Janssen. *See* 6/3/24 Tr. 5596:24–5602:24; Exhibit A-1 at 56 (Shaked Demo). He testified, for example, that removing the 6.3 percent of influenced physicians who received only one marketing contact from Janssen resulted in a reduction of damages by 1-2 percent. *See* 6/3/24 Tr. 5598:13–5599:08. Shaked also testified that his damages calculations did not include any rebates paid back to government payors, which are typically 3 percent. *See* 6/3/24 Tr. 5582:14–5587:09.

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<sup>57</sup> Jena himself, in his rebuttal report in this case, purported to cut Shaked's damages calculations in half based on these very facts that were before the jury. *See* Exhibit A-2.

The jury was thus free to accept or reject portions of the damages and false claims associated with each of Prezista and Intelence, specific promotional claims, and/or specific government payors in their general verdict. At bottom, it is not Janssen's prerogative to second-guess the jury's verdict merely because it claims it cannot divine how the jury arrived at its final figures.

Janssen's lone citation to an antitrust case, *R.S.E., Inc. v. Pennsy Supply, Inc.*, 523 F. Supp. 954, 970 (M.D. Pa. 1981), for the proposition that a jury "may not simply 'reduce the figures to reflect only compensable losses' in the absence of a 'reduction formula prepared by an expert'" is wholly inapplicable here. Def. Br. at 47–48. In that case, the jury did not render a verdict for the plaintiff at all. Rather, the jury found for the defendant on one claim and hung on all remaining claims as to both liability and damages. *R.S.E.*, 523 F. Supp. at 972. The district court granted the defendants' Rule 50(b) motion and held that plaintiff's lost profits damages model in its entirety was "unsupported by the facts of record" and "so speculative" that it rendered "the lost profit damage model, or any verdict awarded thereon, unreasonable." *Id.* at 970.<sup>58</sup>

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<sup>58</sup> Moreover, the court in *R.S.E.* held that the financial records underlying plaintiff's damages model were unreliable. *Id.* Finally, the court held that plaintiff "failed to provide sufficient evidence to the jury that would provide it with the raw data it would need to arrive at a damage award without resorting to guesswork or speculation." *Id.* at 970–71. In contrast, Relators presented a reliable damages model, thoroughly attested to by Shaked, that was predicated on raw data pulled directly from the claims data for CMS, ADAP, and other data attested to by data

As opposed to the jury in *R.S.E.*, the jury here found Janssen liable for violating the federal and state FCAs and causing the submission of false claims based on Janssen's unlawful promotion of Prezista or Intelence. As the factfinder, the jury was entitled to find fewer false claims and a lower damages figure than the global amounts attested to by Relators' experts—exactly as the parties agreed and as the Court instructed the jury in response to its direct question to the Court during deliberations. *See* 6/13/24 Tr. 8304:8–8306:16; 8311:3–7.

There is no basis for Janssen to claim that the jury “rejected” Shaked's damages model and “substituted its own, arbitrary assessment” of the number of false claims and the amount of damages. Def. Br. at 47. As to the number of false claims, the jury found that Janssen caused 159,574 false claims to be submitted as a result of Janssen's violations of the federal FCA. *See* Dkt. 435 at 2 (Verdict Form). The jury further found that the United States sustained \$120,004,736 in damages as a result of those federal FCA violations. *Id.* Those findings amount to \$752 in damages per each individual false claim ( $\$120,004,736 / 159,574 = \$752$ )—which is *the precise amount of damages per false claim attested to by Shaked*. *See* Tr. 6/3/24

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expert Ian Dew. The Court has repeatedly rejected Janssen's attempts to cast Relators' damages evidence as unsupported or unreliable.

at 5485:12–20; *see also* Ex. A-1 at 73 (Shaked Demo) ( $\$446,700,000 / 593,996 = \$752$ ).

Similarly, the total damages separately attributed to the state Medicaid programs as a result of Janssen’s violations of the state FCAs was \$30,001,184—or 20 percent of the total damages awarded. *See* Dkt. 435 at 2, 4–5 (Verdict Form). That amount was also well within the range of evidence the jury had to consider. *See, e.g.*, 6/10/24 Tr. 7617:11–7621:12; *see also* RX 1789 at 35–36.

Whatever combination of testimony or documentary evidence, and whatever permutation of Prezista or Intelence promotional claims, government payor mix, rebates, OL prescribing rates, marketing contacts, or other adjustments the jury may have made in arriving at a verdict lower than the global totals attested to by Shaked, the final amounts are well within the ranges attested to by Relators’ and Janssen’s experts and cannot be disturbed.<sup>59</sup>

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<sup>59</sup> *See, e.g., In re Urethane Antitrust Litig.*, 768 F.3d 1245, 1268 (10th Cir. 2014) (“Dow assumes that the jury could not adjust Dr. McClave’s damages figure without his ‘underlying calculations’ or some other ‘tool.’ This assumption is incorrect, for a jury can reduce an expert’s calculations on damages even when unable to ‘run the exact numbers and calculations of [a damages] model with ‘mathematical certainty.’”) (internal citations omitted) (quoting *Medcom Holding v. Baxter Travenol Labs., Inc.*, 106 F.3d 1388, 1400–01 (7th Cir. 1997); *see also Russo v. Ballard Med. Prods.*, 550 F.3d 1004, 1018 (10th Cir. 2008) (rejecting the defendant’s argument that the jury’s award “exceeded what the record evidence could support” when the jury awarded an amount lying “somewhere in between the extremes suggested by the evidence received at trial”); *see also In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 533–34 (6th Cir. 2008) (rejecting the defendant’s argument that “the jury must have resorted to speculation” to arrive at a damages

The jury's findings on the number of false claims and the amount of damages were supporting by ample evidence. Performing these estimations is the quintessential role of a jury, and Janssen's challenges on Rule 50(b) must be denied.

**D. The Jury's Findings On Federal Damages And The Number Of Claims Must Likewise Be Upheld.**

Janssen next contends that the jury's findings on federal damages and the number of false claims must be "vacated" because (1) Relators' state-law claims "fail as a matter of law" and the number of false claims "includes federal and state claims" that cannot be disaggregated; and (2) the jury's "federal" damages finding comprises payments by Medicare, ADAP, and "(to the extent of the federal portion) Medicaid," which Janssen contends cannot be "separated out" based on the evidence in the record. Def. Br. at 49.

Janssen is wrong again. The entirety of Janssen's argument here turns on its contention that Relators' state-law claims fail as a matter of law. Def. Br. at 49. Because Relators' state-law claims were properly submitted and were supported by ample evidence, as discussed *supra* Section II, Janssen has no valid basis for

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award of \$11.5 million, when the expert calculated damages of \$20.9 million); *see also Tuf Racing Prods., Inc. v. Am. Suzuki Motor Corp.*, 223 F.3d 585, 591 (7th Cir. 2000) (rejecting the defendant's argument that the jury's award should be set aside as "speculative" when the plaintiff's expert calculated damages of \$1.2 million, but "the jury awarded only a bit more than 10 percent of that").

contesting the jury's verdict as to the number of false claims or the amount of federal damages.

More puzzling is why Janssen contends that "the jury's finding of \$120,004,736 in federal damages constitutes an unknown combination of dollars paid by Medicare, Medicaid and ADAP" or that "its finding of 159,574 claims constitutes an unknown combination of claims made to those payors." Def. Br. at 50. The "federal damages" that the jury assessed constitute harm the United States sustained as a result of Janssen's violations of the federal FCA. *See* Dkt. 435 at 2, Question Three (Verdict Form). That amount, as Relators proved and argued, consists of federal funds for Medicare and ADAP. Damages sustained by state Medicaid programs (to which the Court's Instruction No. 23 exclusively pertained) were separately assessed by the jury. *Id.* at 5, Question Eight; *see* Rel. Br. MNT at 23–25, which Relators incorporate herein.

Janssen further ignores the record evidence of the breakdown of Shaked's requested damages (and the corresponding false claims) by each of Janssen's four OL promotion schemes for Prezista and Intelence, broken out by Medicare, ADAP, and Medicaid damages. *See supra* Section III.C at 61. Seizing upon a jury question regarding the location of that evidence in a voluminous record, Janssen falsely claims that "there is no basis for these quantities and no evidence in the record that would support any other numbers in their place." Def. Br. at 50, 51. The jury heard

the evidence, had access to the trial transcripts of both Shaked and Jena, was directed by the Court to “review all the evidence,” and did in fact deliberate. That the jury subsequently returned a verdict within the range and in the same proportions of that very evidence should not be a surprise—that is how juries work. Regardless, Janssen cannot now pretend that the evidence of “federal damages” and corresponding claims does not exist merely by ignoring the record.

Because Relators proved their claims with respect to ADAP and Medicaid just as with Medicare, Janssen’s challenge fails.

#### **IV. JANSSEN’S OTHER ARGUMENTS SHOULD BE REJECTED**

##### **A. The Government Action Bar and Public Disclosure Bar Do Not Apply Here**

Janssen’s throwaway arguments that Relators’ claims should be dismissed due to the FCA’s government action and public disclosure bars “in light of the 2010 CIA” are legally and factually meritless. Dkt. 473-1 at 59. Janssen previously moved *in limine* to exclude the CIAs at trial, arguing they were an “irrelevant” and “distracting sideshow” that would “confuse the jurors and waste the parties’ and the Court’s time.” Dkt 319-1 at 30, 32. The Court, acknowledging the CIAs were imposed for conduct distinct from Janssen’s illegal promotion here, ultimately admitted the CIAs for a limited purpose and barred the jury from considering them for propensity. Dkt. 424-11 at 38–39 (Instruction No. 20).

Now, after the jury has rendered its verdict, Janssen has again pivoted to an unsupportable position. According to Janssen’s brief, the 2010 CIA—which Janssen previously represented is *irrelevant*—is actually so similar to the fraud Relators proved at trial that this case should have never been heard based on the government action and public disclosure bars. This argument is meritless.

**1. The “Government Action Bar” is inapplicable.**

First, Janssen argues that Relators’ claims are barred by the government action bar “because of the prior FCA action and resulting 2010 CIA[,]” which similarly “focused on off-label marketing[.]”<sup>60</sup> Dkt 473-1 at 51. Section 3730(e)(3) bars *qui tam* actions that are “based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.” As one court explained:

[T]he government action inquiry is essentially a test of factual similarity. If a relator’s allegations are the same as allegations already made by the government, or are similar enough to be characterized as feeding off of the government’s allegations, the government action bar

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<sup>60</sup> Janssen also argues that “the prior FCA suit and resulting 2010 CIA created an ongoing proceeding in which the HHS-OIG was looking for and could have penalized Janssen” for its illegal promotion of Prezista and Intelence. Def. Br. at 60. Janssen’s argument should be given no weight as it neither cites any authority for this assertion nor argues that the so-called “ongoing proceeding” is a civil suit or a penalty proceeding within the meaning of the government action bar. See *United States ex rel. Chiba v. Guntersville Breathables, Inc.*, 421 F.Supp.3d 1241, 1257–58 (N.D. Ala. 2019) (holding an investigation outside of an administrative civil money penalty proceeding cannot trigger the government action bar).

applies. By contrast, if a relator's case '*is seeking to remedy fraud that the government has not yet attempted to remedy,*' the government action bar does not apply.

*Sturgeon v. Pharmerica Corp.*, 438 F.Supp.3d 246, 262 (E.D. Pa. 2020) (quoting *United States ex. rel. S. Praver and Co. v. Fleet Bank of Maine*, 24 F.3d 320, 328 (1st Cir. 1994)) (emphasis added).

In support, Janssen cites only *United States ex rel. Bennett v. Biotronick, Inc.*, 876 F.3d 1011, 1015 (9th Cir. 2017), in which the Ninth Circuit affirmed the application of the government action bar because it was based on *the exact same allegations and transactions* as an earlier-filed suit the Government had settled.

That is not the case here. Even assuming that the unnamed "prior FCA action" and 2010 CIA qualify as "government actions" sufficient to trigger the government action bar, Relators' claims are clearly not "based upon" or the same as the allegations regarding the OL promotion (by a different J&J subsidiary) of the anticonvulsant drug Topamax, which is an FDA-approved drug used to treat epilepsy. Relators' claims involve different drugs (Prezista and Intelence), a different time period, and a different Janssen affiliate. Janssen cannot claim that Relators' case is barred here merely because a Janssen affiliate committed fraud using similar methods.

**2. The “Public Disclosure Bar” is not applicable here.**

Janssen argues that Relators’ claims should be dismissed based on the FCA’s public disclosure bar. This too is without merit. There has never been a public disclosure of substantially the same allegations or transactions as Relators’ claims and, in any event, Relators qualify as original sources.

As an initial matter, the FCA’s public disclosure bar was amended on March 23, 2010 to allow the Government a right to veto any application of the bar. The Government here is exercising that right, *see* Dkt. 478, and, thus, Relators’ claims from March 23, 2010 through 2014 cannot be dismissed.<sup>61</sup>

The public disclosure bar only applies to dismiss an action or claim if substantially the same allegations or transactions of the fraud were publicly disclosed through certain statutorily-identified sources, but not if the relator is an “original source” of the information. 31 U.S.C. § 3730(e)(4)(A). The 2010 CIA does not involve the same allegations and transactions. As noted above, the 2010 CIA contains only a single vague allegation of unlawful promotion that concerns

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<sup>61</sup> In addition, the public disclosure bar is no longer jurisdictional since the 2010 FCA amendment and, therefore, must be raised as an affirmative defense. *See United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 915 (4th Cir. 2013) (holding the public disclosure bar is no longer jurisdictional, and that “[t]he retroactivity inquiry looks to when the underlying conduct occurred, not when the complaint was filed.”). Janssen failed to assert it as an affirmative defense and, thus, it has been waived. *See United States ex rel. Chorchos for Bankruptcy Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 80 (2d Cir. 2017) (defendant failed to raise the public disclosure bar as an affirmative defense and, thus, it was waived on appeal).

*Topamax*—a drug used to treat epilepsy. This is not “substantially the same” as the facts alleged and proven by Relators at trial regarding Prezista and Intelence. *See Omnicare*, 903 F.3d at 83. If the 2010 CIA could bar subsequent *qui tam* suits based on allegations of OL marketing of *other drugs*, then the 2013 CIA (addressing the OL marketing of Risperdal committed by a different Janssen affiliate) would not exist, and Janssen would effectively be immune from any suit related to other OL marketing using the same fraudulent tactics. This result is nonsensical.

In any event, the public disclosure bar does not apply because Relators are original sources. 31 U.S.C. § 3730(e)(4)(A). Ms. Brancaccio and Ms. Penelow have direct and independent knowledge of the information, as demonstrated at trial, and voluntarily provided such information to the government. *Id.*, at § 3730(e)(4)(B).

**B. There is no Constitutional Bar to Relators’ Claims**

Finally, Janssen requests the extraordinary relief of holding the FCA’s *qui tam* provision, allowing a private citizen to bring an action on behalf of the Government, unconstitutional in its entirety. Janssen argues the *qui tam* provision violates Article II because “[t]he government imposes no limitation on the scope of a relator’s lawsuit” and “does not impose sufficient control on the exercise of executive power by private relators in non-intervened cases.” Def Br. at 54–55. Janssen is mistaken.

As acknowledged by the Supreme Court, the Government maintains significant control over a *qui tam* suit, regardless of whether the Government

intervenes or not. *United States, ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 425 (2023). “[T]he Government’s views are entitled to substantial deference” and an FCA suit “alleges injury to the Government alone.” *Id.* at 437. The Government may settle the case and can veto any voluntary dismissal or settlement by a relator. 31 U.S.C. § 3720(b)(1), (c)(2)(B). And, contrary to Janssen’s assertion, the Government holds the ultimate power over an FCA suit—the power to end it. At any time, the Government may choose to intervene and dismiss an FCA suit where it has “good grounds for thinking that [a] suit would not do what all *qui tam* actions are supposed to do: vindicate the Government’s interests.” *Id.* at 437.

Since the FCA’s inception in 1863, every federal circuit to consider the *qui tam* provision’s constitutionality has upheld it.<sup>62</sup> There is a “long tradition of *qui tam* actions in England and the American Colonies.” *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 774, 787 (2000). “Indeed, the Founding Fathers and the First Congress enacted a number of statutes authorizing *qui tam* actions[,]” which “have been used throughout American and English history as a means to discover and to prosecute fraud against the national treasuries.” *Riley v. St.*

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<sup>62</sup> See, e.g., *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148 (2d Cir. 1993); *Riley v. St. Luke’s Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001) (en banc); *United States ex rel. Taxpayers Against Fraud v. Gen Elec. Co.*, 41 F.3d 1032 (6th Cir. 1994); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743 (9th Cir. 1993); *United States ex rel. Stone v. Rockwell Int’l Corp.*, 282 F.3d 787 (10th Cir. 2002).

*Luke's Episcopal Hosp.*, 252 F.3d 749, 752 (5th Cir. 2001) (citing *Stevens*, 529 U.S. at 792). Just last month, the District Court for the Southern District of Florida upheld the *qui tam* provision's constitutionality, noting "the abundance of other courts that have balked at [this] argument" and stating that "if the First congress found the mechanism constitutionally appropriate, it would be difficult to justify reaching the opposite conclusion from the very Framers themselves." Order on Mot. to Dismiss at 23, *United States ex rel. Butler v. Shikara*, No. 20-80483-CV (S.D. Fla. Sept. 6, 2024); *but see U.S. ex rel. Zafirov v. Florida Medical Associates, LLC*, No. 8:19-cv-1236, 2024 U.S. Dist. LEXIS 176626 (M.D. Fla. Sept. 30, 2024) (holding, breaking with all existing precedent, the *qui tam* provisions of the FCA unconstitutional). Accordingly, this Court should reject Janssen's argument that the FCA's *qui tam* provision violates Article II. *See Am. C. L. Union v. Holder*, 673 F.3d 245, 252 (4th Cir. 2011) (holding "lower federal courts should not 'pass on questions of constitutionality . . . unless such adjudication is unavoidable'").

The Court should deny Janssen's constitutional challenge.

## V. CONCLUSION

Relators respectfully request that the Court deny Janssen's Motion in its entirety.

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